DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 410, 414, 415, 423, 424, and 425

[CMS–1734–F, CMS–1734–IFC, CMS–1744–F, CMS–5531–F and CMS–3401–IFC]

RIN 0938–AU10, 0938–AU31, 0938–AU32, and 0938–AU33

Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19

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

ACTION: Final rule and interim final rule.

SUMMARY: This major final rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program requirements for Eligible Professionals; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; Medicare enrollment of Opioid Treatment Programs; payment for office/outpatient evaluation and management services; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA–PD plan and Medicare Diabetes Prevention Program (MDPP) expanded model Emergency Policy. This final rule also finalizes certain provisions of the interim final rules with comment period that CMS issued on March 31, 2020, May 8, 2020, and September 2, 2020 in response to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19). This rule also establishes coding and payment for virtual check-in services and for personal protective equipment (PPE) on an interim final basis.

DATES: *Effective Date:* The regulations in the final rule are effective on January 1, 2021.

Applicability date: The policies in this final rule are applicable on January 1, 2021, except as follows:

(1) The revisions to 42 CFR 400.200 and 425.611(b)(1)(ii) are applicable retroactively to the start of the PHE for COVID–19 on January 27, 2020. (See discussions in sections II.J. and III.G.5.d.(2) of this final rule, respectively.)

(2) The revisions to 42 CFR 425.400(c)(2) are applicable retroactively for the performance year starting on January 1, 2020. (See discussion in section III.G.5.e.(3) of this final rule.)

Comment date: Comments will be accepted/considered ONLY on the ''Interim Final Rule with Comment Period for Coding and Payment of Virtual Check-in Services'' contained in section II.D. of the preamble of this document and ''Interim Final Rule with Comment Period for Coding and Payment for Personal Protective Equipment (PPE)'' contained in section II.H. of the preamble of this document. To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 1, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1734–IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1734–IFC,P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1734–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Jamie Hermansen, (410) 786–2064, for any issues not identified below.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, PFS specialty-specific impacts, and the interim final rule with comment period for coding and payment for PPE.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Emily Yoder, (410) 786–1804, Donta Henson, (410) 786–1947, and Patrick Sartini, (410) 786–9252, for issues related to telehealth, other services involving communications technology, and interim final rule with comment period for coding and payment of virtual check-in services.

Liane Grayson, (410) 786–6583, for issues related to care management services and remote physiologic monitoring services.

Emily Yoder, (410) 786–1804, Christiane LaBonte, (410) 786–7237, Ann Marshall, (410) 786–3059, and Patrick Sartini, (410) 786–9252, for issues related to payment for office/outpatient evaluation and management visits.

Christiane LaBonte, (410) 786–7237, and Cindy Bergin, (401) 786–1176, for issues related to teaching physician services.

Roberta Epps, (410) 786–4503, and Regina Walker-Wren, (410) 786–9160, for issues related to supervision of diagnostic tests.

Ann Marshall, (410) 786–3059, for issues related to incident to pharmacist services.

Gift Tee, (410) 786–9316, for issues related to therapy services.

Sarah Leipnik, (410) 786–3933, for issues related to medical record documentation.

Lindsey Baldwin, (410) 786–1694 and Terry Simananda, (410) 786–8144, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Laura Ashbaugh, (410) 786–1113, for issues related to Clinical Laboratory Fee

Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions

Joseph Schultz, (410) 786–2656, for issues related to opioid treatment program provider enrollment regulation updates for institutional claim submissions.

Lisa Parker, (410) 786–4949, for issues related to RHCs and FQHCs, primary care management services, and the FQHC market basket.

Rachel Katonak, (410) 786–8564, or JoAnna Baldwin (410) 786–7205, for issues related to comprehensive screenings for seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

David Koppel, (303) 844–2883, or Elizabeth LeBreton (202) 615–3816 for issues related to the Medicaid Promoting Interoperability Program.

Fiona Larbi, (410) 786–7224, or Sabrina Ahmed, (410) 786–7499, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard, quality reporting requirements and finalization of Shared Savings Program provisions from the March 31st COVID–19 IFC.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment, repayment mechanism requirements, and finalization of Shared Savings Program provisions from the May 8th COVID–19 IFC.

Cheryl Gilbreath, (410) 786–5919, for issues related to home infusion therapy benefit.

Heather Hostetler, (410) 786–4515 for issues related to removal of selected national coverage determinations.

Joella Roland, (410) 786–7638, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan.

Edmund Kasaitis, (410) 786–0477, for issues related to Part B drug payment and Food Drug & Cosmetic Act section 505(b)(2) drug products.

Elizabeth Holland, (410) 786–1309, for issues related to updates to certified electronic health record technology due to the 21st Century Cures Act.

Julia Venanzi, (410) 786–1471, for issues related to the Hospital Inpatient Quality Reporting (IQR) Program.

Cynthia Hake, (410) 786–3404, for issues related to HCPCS Level II codes.

Amanda Rhee, (410) 786–3888, for the Medicare Diabetes Prevention Program (MDPP) expanded model emergency policy.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Brittany LaCouture, (410), 786–0481, for inquiries related to Alternative Payment Models (APMs).

Patricia Taft, (410) 786–4561, for issues related to the Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the internet on the CMS website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2021 PFS final rule, refer to item CMS–1734–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this final rule includes provisions related to other payment policy changes that are addressed in sections III. and IV. of this final rule.

We are issuing an interim final rule with comment period (IFC) to establish coding and payment for virtual check-in services to support the continuing need for coding and payment to reflect the provision of lengthier audio-only services outside of the PHE for COVID–19, if not as substitutes for in-person services, then as a tool to determine whether an in-person visit is needed, particularly as beneficiaries may still be cautious about exposure risks associated with in-person services. We are also issuing an interim final rule with comment period to establish coding and payment for PPE as a bundled service and certain supply pricing increases in recognition of the increased market-based costs for certain types of PPE.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work; practice expense (PE); and malpractice (MP) expense. In addition, the statute requires that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are establishing RVUs for CY 2021 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes

discussions and provisions regarding several other Medicare Part B payment policies.

Specifically, this final rule addresses:

- Practice Expense RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Telehealth and Other Services Involving Communications Technology, and the Interim Final Rule with Comment Period for Coding and Payment for Virtual Check-in Services (section II.D.)
- Care Management Services and Remote Physiologic Monitoring Services (section II.E.)
- Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the PHE for COVID–19 (section II.F.)
- Scopes of Practice and Related Issues (section II.G.)
- Valuation of Specific Codes, and the Interim Final rule with Comment Period for Coding and Payment for Personal Protective Equipment (PPE) (section II.H.)
- Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Services Furnished by Opioid Treatment Programs (OTPs) (section II.I.)
- Technical Correction to the Definition of Public Health Emergency (section II.J.)
- Clinical Laboratory Fee Schedule (section III.A.)
- Opioid Treatment Program Provider Enrollment Regulation Updates for Institutional Claim Submissions (section III.B.)
- Payment for Primary Care Management Services in RHCs and FQHCs (section III.C.)
- Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Rebasing and Revising of the FQHC Market Basket (section III.D.)
- Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (section III.E.)
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services (section III.H.)
- Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020 (section III.I.)
- Removal of Selected National Coverage Determinations (section III.J.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA–PD plan (section III.K.)
- Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act (section III.L.)
- Updates to Certified Electronic Health Record Technology Requirements in the Promoting Interoperability Program, Quality Payment Program, and Hospital Inpatient Quality Reporting Program due to the 21st Century Cures Act (section III.M.)
- Establishing New Code Categories (section III.N.)
- Medicare Diabetes Prevention Program (MDPP) expanded model emergency policy (section III.O.)
- Updates to the Quality Payment Program (section IV.)
- Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes (section V.)
- Waiver of Delay in Effective Date for this Final Rule (section VI.)
- Collection of Information Requirements (section VII.)
- Regulatory Impact Analysis (section VIII.)

2. Provisions Related to the PHE for COVID–19

The United States is currently responding to an outbreak of respiratory disease caused by a novel (new) coronavirus. This virus has been named ''severe acute respiratory syndrome coronavirus 2'' (''SARS-CoV–2''), and the disease it causes has been named ''coronavirus disease 2019'' (''COVID–19''). On January 31, 2020, the Secretary determined that a PHE existed nationwide as a result of the consequences of the COVID–19 pandemic (hereafter referred to as the PHE for COVID–19). On March 13, 2020, President Trump declared the COVID–19 pandemic a national emergency. Effective, October 23, 2020, the Secretary renewed the January 31, 2020 determination that a PHE exists and has existed since January 27, 2020. (Note: This declaration was previously renewed on April 21, 2020 and July 25, 2020.)

As the healthcare community continues to establish and implement recommended infection prevention and control practices, regulatory agencies operating under appropriate waiver authority during the PHE for COVID–19 are also working to revise and implement regulations that support these healthcare community infection prevention and treatment practices. We addressed some of these regulations in three previous interim final rules with comment period (IFCs):

- The ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' IFC appeared in the April 6, 2020 **Federal Register** (85 FR 19230) with an effective date of March 31, 2020 (hereafter referred to as the ''March 31st COVID–19 IFC'');
- The ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' IFC appeared in the May 8, 2020 **Federal Register** (85 FR 27550) with an effective date of May 8, 2020 (hereafter referred to as the ''May 8th COVID–19 IFC''); and
- The ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' IFC appeared in the September 2, 2020 **Federal Register** (85 FR 54820) with an effective date of September 2, 2020 (hereinafter referred to as the ''September 2nd COVID–19 IFC).

In this final rule, we are finalizing certain provisions of the March 31st, May 8th, and September 2nd COVID–19 IFCs.

We indicated in the CY 2021 PFS proposed rule (85 FR 50140 and 50147) our intent that for certain provisions of the March 31st, May 8th, and September 2nd COVID–19 IFCs, we would respond to comments received in this final rule. In this final rule, we are responding to public comments and finalizing certain provisions of the March 31st, May 8th, and September 2nd COVID–19 IFCs.

3. Summary of Costs and Benefits

We have determined that this final rule is economically significant. For a detailed discussion of the economic impacts, *see* section VIII. of this final rule.

4. Waiver of the 60-Day Delay in Effective Date for the Final Rule

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190

locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS CoV 2'' and the disease it causes has been named ''Coronavirus disease 2019'' (abbreviated ''COVID–19'').

Due to the significant devotion of resources to the COVID–19 response, as discussed in section VI. of the preamble of this final rule, we are hereby waiving the 60-day delay in the effective date for this final rule as proposed, and replacing it with a 30-day delay in the effective date for this final rule.

II. Summary of the Proposed Provisions, Analysis of and Response to Public Comments, and the Provisions of the Final Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the RVUs

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended by section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA '97) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA '97 provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some resource costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those specific facility resource costs is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept

these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA '97 amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the states, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VIII. of this final rule, the Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. Please refer to the CY 2020 PFS final rule for a discussion of the last GPCI update (84 FR 62615 through 62623).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS' Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty

that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2021 PFS Final Rule PE/HR'' on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

As noted above, we have established PE/HR values for various specialties without SMS or PPIS survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. On this note, stakeholders have raised concerns regarding the appropriate specialty crosswalk used for home PT/INR monitoring services. These services are currently classified under the independent diagnostic testing facilities (IDTF) specialty for PE/HR purposes, due to a lack of survey data for these services, and stakeholders have suggested to CMS that this specialty does not reflect the indirect costs associated with furnishing these services. Stakeholders have raised concerns that the practice pattern of PT/INR monitoring services are markedly different from that of the dominant parent specialty as most of the services are furnished remotely and require long-term relationship with beneficiaries similar to chronic therapy. Stakeholders also stated that this is a unique request due to the lack of home PT/INR monitoring supplier involvement in the last PPIS, and that payments for these services are derived from previously used supplemental survey data from the Association for Quality Imaging (AQI), blended with supplementary survey data from the American College of Radiology (ACR)—neither of which reflect indirect cost inputs for home PT/INR monitoring.

Therefore, we are solicited comment from the public regarding the most accurate specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services. We sought information on any additional costs associated with these services that are not reflected in our currently assigned PE/HR for independent diagnostic testing facilities, as well as which specialties would best capture these costs through the use of a crosswalk.

We received public comments on our comment solicitation regarding the most accurate specialty crosswalk to use for indirect PE for home PT/INR monitoring services. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had numerous concerns about the labor, supplies, equipment, and utilization associated with home PT/INR monitoring services. Commenters questioned why the typical clinical staff type for these services is an RN when 95 percent of Medicare claims for HCPCS code G0248 indicate that the service is instead furnished by the IDTF provider specialty. Commenters also questioned the clinical staff labor associated with HCPCS code G0249, as the commenters stated that they did not believe that an electrodiagnostic technologist is the appropriate clinical staff type since these technologists furnish cardiac event monitoring (CEM)-related services, not PT/INR monitoring services. Commenters stated that they believed a patient education booklet is likely a duplicative supply item for HCPCS code G0248, as the patient is expected to have already received booklet(s) related to anticoagulation at previous physician visits, and a free booklet is also supplied with INR meters. Commenters also questioned the discrepancy between the description and billing rules for this code, which state that four tests are performed, and the supply details for this code, which include supplies for six tests. Commenters stated that CMS should decrease the minutes assigned to the home INR monitor (EQ031) equipment and questioned whether this frequency of physician review meets Medicare medical necessity criteria for all patients receiving such services. One commenter submitted a shipping invoice for the INR test strip (SJ055) supply.

Response: We appreciate the additional information provided by the commenters regarding the direct PE inputs and claims data utilization for home PT/INR monitoring services. However, our comment solicitation

sought information regarding the most accurate specialty crosswalk to use for indirect PE as well as which specialties would best capture these costs through the use of a crosswalk. We did not propose to make revisions to the direct PE inputs or conduct a review of the Medicare claims data. Although we appreciate the information provided by the commenters, we are not finalizing any changes to the direct PE inputs for home PT/INR monitoring services. With regard to the shipping invoice for the INR test strip supply, we welcome the submission of invoices or other pricing information as part of our ongoing market-based supply and equipment pricing update. However, this invoice listed the transportation costs of shipping the test strips and not the price of the test strips themselves, and as a result we were unable to make use of it.

Comment: Many commenters stated that there were inherent differences between home PT/INR monitoring services and independent diagnostic testing facilities. Several commenters stated that given the significant changes to technology and associated decrease in costs since the IDTF PE/HR value was first developed, they believed that many of the indirect PE inputs originally recognized for IDTFs in 2007 no longer apply in 2020 and home PT/INR monitoring services should no longer be crosswalked to them. Several commenters stated that typical IDTF services include the use of large, capital-intensive equipment while home PT/INR monitoring services typically involve the use of equipment by a patient in his/her home, frequently intended for use for the remainder of the patient's life—more like a therapeutic device than a diagnostic one. Several commenters emphasized that PT/INR monitoring services are very different from typical imaging and scanning services provided by IDTFs, and because there are so few suppliers of home PT/INR monitoring services, the distribution of direct and indirect costs and the indirect practice cost index (IPCI) applied to IDTFs do not accurately reflect indirect resources expended by the specialty suppliers of home PT/INR monitoring.

Several commenters provided feedback regarding the most accurate specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services. Several commenters submitted data indicating that the direct to indirect cost percentages used to furnish home PT/INR monitoring are in the range of 31:69 rather than the approximately 50:50 currently considered in determining the PE RVUs for these services as IDTFs. These commenters recommended a crosswalk to the Pathology or All Physicians specialty type based on the submitted data. One commenter stated that they were not equipped to say which specific indirect factors may be optimal for crosswalk due to a lack of information on direct and indirect cost data from the suppliers but did wish to highlight the importance of ensuring sure that home PT/INR monitoring rates are adequate to assure access. Several commenters stated that the payment rates for these services have fallen dramatically over the past several years and they were very concerned about the impact of these cuts on patient access to these critically important services.

Response: We appreciate the detailed feedback from the commenters regarding home PT/INR monitoring services and especially the submission of data associated with the direct to indirect cost percentages. We also share the concerns of the commenters regarding maintaining access to care for these services. After consideration of the comments, we are finalizing a crosswalk to the General Practice specialty to use for indirect PE when it comes to home PT/INR monitoring services (HCPCS codes G0248, G0249, and G0250). The data submitted by the commenters indicated that the direct to indirect cost percentages to furnish home PT/INR monitoring are in the range of 31:69, similar to the ratio associated with the General Practice specialty. We also share the concerns of the commenters who were uncertain which specific indirect factors may be optimal for crosswalking due to a lack of information, and we believe that the broad nature of the General Practice specialty will serve as a more accurate proxy for home PT/INR monitoring services as opposed to trying to select a more specific specialty designation.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect

cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We received public comments on the proposed list of expected specialty assignments for CY 2021. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that the 2021 expected specialty assignment for the low volume services code list included a number of services that were reassigned from cardiac surgery to thoracic surgery in CY 2020. The commenter identified these services and stated that they had concerns that CMS had erroneously assigned them as thoracic surgery procedures instead of cardiac surgery procedures. The commenter requested that CMS to correct the list and permanently assign the identified codes to the requested thoracic surgery specialty assignment.

Response: We finalized a proposal in CY 2020 to update the expected specialty list to accurately reflect a previously finalized crosswalk to thoracic surgery for the services in question. As we stated at the time, we did not finalize a proposal to assign the codes in question to the cardiac surgery specialty. Instead, we finalized a proposal to update the incorrect

documentation in our expected specialty list to accurately reflect a previously finalized crosswalk to thoracic surgery for these services. The previously finalized assignment of the cardiac specialty to these services has been in place since the CY 2012 rule cycle, and we believe that the expected specialty list should be updated to reflect the correct specialty assignment. We did not propose to make further changes to the anticipated specialty assignment of these codes for CY 2021 and we are not finalizing any changes. We direct readers to the discussion of this topic in the CY 2020 PFS final rule (84 FR 62574 through 62578) and we reiterate again that we do not anticipate this finalized proposal having a discernible effect on the valuation of the affected codes due to the similarity between the cardiac surgery and thoracic surgery specialties.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (*Note:* For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- Crosswalk *certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical *therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- Work *RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1-(1/((1 + interest rate) ∧ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally 150,000 minutes.
usage = variable, *see* discussion below in this final rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, *see* discussion below in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

We received public comments on equipment utilization rate assumptions. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS review the utilization assumptions for equipment due to decreased practice capacity during the public health emergency (PHE) for COVID–19. Commenters stated that equipment was used less frequently than normal and that this should be reflected in the equipment utilization rate. Commenters stated that any modifications to the equipment utilization during the public health emergency also should not be subject to budget neutrality.

Response: We disagree with the commenters that utilization assumptions for equipment should be revisited as part of the public health emergency. While we agree that many services had a reduced volume of Medicare beneficiaries at times during the 2020 calendar year, we note that equipment costs under the PFS are amortized across the full useful life of the equipment which in the vast majority of cases is 5–10 years. We believe that it would distort relativity to apply a temporary decrease in utilization caused by the public health emergency to the pricing structure of the equipment's full useful life duration. We also note that we do not have statutory authority to exempt any modifications to the equipment utilization assumptions from budget neutrality calculations.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS proposed rule, we noted that stakeholders including the RUC, specialty societies, and other commenters suggested a useful life of less than 1 year for several of the new equipment items for CY 2021, and as low as 3 months in one case. We have rarely, if ever, received requests for equipment useful life of less than one

year in duration and note that these very short useful life durations are significantly lower than anything in our current equipment database, and if finalized would represent major outliers when compared to the rest of the equipment. Table 3 details the distribution of useful life durations of the equipment currently in our database:

TABLE 3: Equipment Life Durations

Useful Life Duration	Number of Equipment Codes	Percentage of Total
15 years or greater	37	5%
10-14 years	159	20%
6-9 years	210	27%
5 years	313	40%
3-4 years	54	7%
1-2 years	4	1%

As Table 3 demonstrates, the vast majority of equipment items have a useful life duration of 5 to 10 years, and only 4 out of the 777 equipment codes have a useful life duration of less than 3 years. We also noted that due to the formula used to calculate the equipment cost per minute, decreasing the useful life of any equipment item from 5 years to 3 months has the same effect as increasing the price of the equipment 20 times over. In other words, decreasing the useful life from 5 years to 0.25 years has the same multiplicative effect as increasing the price of the equipment from $5,000 to 100,000 due to the formula listed above. Since we currently do not have any equipment items in our database with a useful life of less than one year, we proposed a clarification on how to address these cases.

We disagreed that assigning a useful life at these very short durations would be typical for new equipment, especially in light of the data provided by the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' reference. The equipment life durations listed in Table 3 were finalized over the last 15 years through the use of this reference material. We noted concerns that assigning very low useful life durations to equipment items would fail to maintain relativity with other equipment on the PFS, effectively assigning a much higher price than other equipment items with more typical useful life durations. We noted that we believe that equipment items with very low useful life durations represent outlier cases that are not handled appropriately by the current equipment methodology and which we clarified through this rulemaking. We also noted that the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. Our current equipment formula is not designed to address cases in which equipment is replaced multiple times per year, and we believe that applying a multi-year depreciation in these situations would not be reflective of market pricing. We noted that we did not believe that items which are replaced on a monthly basis can be accurately priced using a formula which assumes they will be in use for years at a time, and that the use of such a formula would distort relativity with the overwhelming majority of equipment items which are in use for 5–10 years.

Therefore, we proposed to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. We noted that we believe that this is the most accurate way to incorporate these short equipment life durations within the framework of our current methodology. In the rare cases where items are replaced every few months, we noted that we believe that it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For example, we proposed to establish the EECP compression equipment package (SD341) and the EECP electrical equipment package (SD342) as disposable supplies instead of equipment items as described in the Valuation of Specific Codes (section II.H. of this final rule) portion of the preamble. We noted that we expect these situations to occur only rarely, and we will evaluate them on an individual case-by-case basis. Our criteria will be based on whether or not the item in question could be more accurately classified as a disposable supply while maintaining overall relativity within our PE methodology. We welcomed additional comments from stakeholders regarding the subject of useful life durations for new equipment items with unique useful life durations as described above and any additional suggestions on alternative ways to incorporate these items into our methodology or potential wider changes to the equipment cost per minute formula more broadly.

We received public comments on our proposals associated with equipment life duration. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that although they had asked CMS to use 0.75 years as the useful life duration for the radionuclide rod source set (ER044) equipment, the commenter recognized that one year was in accordance with the CMS policy to treat equipment useful life durations of less than one year as having a duration of one year.

Response: We appreciate the feedback from the commenter and the acknowledgment of our proposed policy.

After consideration of the public comments, we are finalizing our proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe that it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations.

- *Maintenance:* This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also

noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

• *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (*see* 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 4.

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose any changes to the equipment interest rates for CY 2021.

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2021 direct PE input public use files, which are available on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, a commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2021, we are continuing to display two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during the review of the recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope, the associated video system, and any scope accessories that might be typical as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems and accessories that are used with scopes.

(1) Scope Equipment

Beginning in the CY 2017 PFS proposed rule (81 FR 46176 through 46177), we proposed standardizing refinements to the way scopes have been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated

prices for the equipment items related to scopes utilized by these services. We did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we noted we could consider proposing to apply to other codes in future rulemaking. We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made further proposals in the CY 2018 PFS proposed rule (82 FR 33961 through 33962) to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We considered creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We stated our belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions, and we believed that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

After considering the comments on the CY 2018 PFS proposed rule, we did not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we supported the recommendation from the commenters to create scope equipment codes on a per-specialty basis for six categories of scopes as applicable, including the addition of a new sixth category of multi-channeled flexible video scopes. Our goal was to create an administratively simple scheme that would be easier to maintain and help to reduce administrative burden. In 2018, the RUC convened a Scope Equipment Reorganization Workgroup to incorporate feedback from expert stakeholders with the intention of making recommendations to us on scope organization and scope pricing. Since the workgroup was not convened in time to submit recommendations for the CY 2019 PFS rulemaking cycle, we delayed proposals for any further changes to scope equipment until CY 2020 in order to incorporate the feedback from the aforementioned workgroup.

(2) Scope Video System

We proposed in the CY 2017 PFS proposed rule (81 FR 46176 through 46177) to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule (81 FR 80188). We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. In the CY 2018 PFS final rule (82 FR 52991 through 52993), we outlined, but did not finalize, a proposal to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. We also described a proposal to increase the price of the scope video system by $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.). With the addition of the LED light (equipment code EQ382 at a price of $1,915), the updated total price of the scope video system would be set at $36,306.

We did not finalize this updated pricing to the scope video system in CY 2018, but we did propose and finalize the updated pricing for CY 2019 to $36,306 along with changing the name of the ES031 equipment item to ''scope video system (monitor, processor, digital capture, cart, printer, LED light)'' to reflect the fact that the use of the ES031 scope video system is not limited to endoscopy procedures.

(3) Scope Accessories

We understand that there may be other accessories associated with the use of scopes. We finalized a proposal in the CY 2017 PFS final rule (81 FR 80188) to separately price any scope accessories outside the use of the scope video system, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

(4) Scope Proposals for CY 2020

The Scope Equipment Reorganization Workgroup organized by the RUC submitted detailed recommendations to CMS for consideration in the CY 2020 rule cycle, describing 23 different types of scope equipment, the HCPCS codes associated with each scope type, and a series of invoices for scope pricing. Based on the recommendations from the workgroup, we proposed to establish 23 new scope equipment codes. For the eight new scope equipment items where we received submitted invoices for pricing, we proposed to replace the existing scopes with the new scope equipment at the same amount of equipment time. This scope replacement involved approximately 100 HCPCS codes in total and was detailed in a table published in the CY 2020 PFS proposed rule (84 FR 40495 through 40498). We noted that we did not receive pricing information along with the workgroup recommendations for the other 15 new scope equipment items. Therefore, although we proposed to establish new equipment codes for these scopes, we did not propose to replace existing scope equipment with the new equipment items as we did for the other eight new scope equipment items for CY 2020.

Following the publication of the CY 2020 PFS proposed rule, commenters provided additional information regarding pricing for the new scope equipment and their associated HCPCS

codes. Based on this information provided by the commenters, we finalized a price for eight additional new scope equipment items and finalized the replacement of the existing scopes with the new scope equipment at the same amount of equipment time for approximately two dozen additional HCPCS codes (84 FR 62593 through 62595). Table 5 lists the CY 2020 finalized price for the new scope equipment codes:

TABLE 5: CY 2020 New Scope Equipment Codes

CMS Code	Scope Equipment Description	Finalized Price
ES070	rigid scope, cystoscopy	
ES071	rigid scope, channeled, hysteroscopy	$6,795.00
ES072	rigid scope, otoscopy	$2,333.98
ES073	rigid scope, nasal/sinus endoscopy	$3,004.75
ES074	rigid scope, proctosigmoidoscopy	
ES075	rigid scope, laryngoscopy	$3,966.08
ES076	rigid scope, colposcopy	$14,500.00
ES077	non-channeled flexible digital scope, hysteroscopy	
ES078	non-channeled flexible digital scope, nasopharyngoscopy	$21,923.43
ES079	non-channeled flexible digital scope, bronchoscopy	
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
ES081	channeled flexible digital scope, cystoscopy	
ES082	channeled flexible digital scope, hysteroscopy	
ES083	channeled flexible digital scope, bronchoscopy	
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
ES090	multi-channeled flexible digital scope, pouchoscopy	$17,360.00
ES091	ultrasound digital scope, endoscopic ultrasound	$0.00
ES092	non-video flexible scope, laryngoscopy	$5,105.97

We noted that although we updated the scope equipment pricing for CY 2020 such that the ES087 and ES089 scopes shared the same price with the ES088 scope, and the ES090 scope shared the same price with the ES085 scope, we did not mean to suggest that these scopes that shared pricing were identical with one another. We assigned the same price to these scopes because they replaced the same current scope equipment codes, and because we did not have individual pricing information for them. We noted in the CY 2021 PFS proposed rule (85 FR 50087) that we remain open to the submission of additional invoices to establish individual pricing for these scopes, and we welcomed more data to help identify pricing for the remaining seven scope equipment codes that still lack invoices.

(5) Scope Proposals for CY 2021

We did not receive further recommendations from the Scope Equipment Reorganization Workgroup organized by the RUC following the publication of the CY 2020 PFS final rule. However, we did receive invoices associated with the pricing of the scope video system (monitor, processor, digital capture, cart, printer, LED light) (ES031) equipment item as part of the review of the Esophagogastroduodenoscopy (EGD) with Biopsy and the Colonoscopy code families. We previously finalized a price of $36,306 for the ES031 equipment based on the sum of component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, $1,750 for the cart, $1,915 for the LED light, and $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.) We received 37 invoices associated with the components of the ES031 scope video system, which averaged out to prices of $21,988.89 for the processor, $16,175.87 for the digital capture device, $6,987.56 for the monitor, $7,922.80 for the printer, $4,945.45 for the cart, and $12,652.82 for the LED light. Based on the sum of these component prices, we proposed to update the price the ES031 scope video system equipment to $70,673.38. We did not propose to include an additional $1,000 to cover the expense of miscellaneous small equipment as the products listed on the component invoices indicated that cost of cables were already included in this significantly higher equipment pricing. We solicited additional comments from stakeholders regarding the pricing of the full ES031 scope equipment system as well as its components.

As part of our market-based supply and equipment pricing transition, we finalized a policy in CY 2019 to phase in any updated pricing established during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, even if invoices are provided as part of the formal review of a code family (83 FR 59473 through 59475). Because the ES031 scope equipment system is utilized by more than 250 HCPCS codes, we proposed to transition this pricing increase over the remaining 2 years of the pricing update,

such that the CY 2021 equipment price will be $53,489.69 before moving to its destination price of $70,673.38 in CY 2022. We noted that this transition policy also applies to the price of the suction machine (Gomco) (EQ235) equipment, which, although it is not a scope, is utilized by approximately 360 HCPCS codes, and therefore, is another example of this pricing transition policy. We proposed to transition the EQ235 pricing increase over the remaining 2 years of the pricing update, such that the CY 2021 equipment price would be $1,981.66 before moving to its destination price of $ $3,195.85 in CY 2022. As we stated previously, this policy was intended to minimize any potential disruptive effects during the pricing transition period due to the high number of services that make use of these very common supply and equipment items included in 100 or more HCPCS codes.

We also received invoices for the colonoscopy videoscope (ES033) and gastroscopy videoscopy (ES034) as part of the review of the Esophagogastroduodenoscopy (EGD) with Biopsy and the Colonoscopy code families. We finalized the replacement of both of these scope equipment items in the CY 2020 PFS final rule (84 FR 62588 through 62590), replacing the colonoscopy videoscope (ES033) with the multi-channeled flexible digital scope, colonoscopy (ES086) equipment item and the gastroscopy videoscopy (ES034) with the multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD) (ES087) equipment item. In both cases, the submitted invoices were nearly identical to the finalized prices for the ES086 ($38,058.81) and ES087 ($34,585.35) equipment. We believe that these invoices reinforce the prices finalized through rulemaking last year, and therefore, we did not propose to further update the prices of these scopes.

We noted that we remain open to further comments regarding the pricing of the remaining seven scope equipment codes that still lack invoices, as well as additional data regarding the pricing of the scope equipment codes that currently share the same price.

We received public comments on our proposals associated with equipment recommendations for scope systems. The following is a summary of the comments we received and our responses.

Comment: Several commenters thanked CMS for updating the prices of the scope video system (ES031) and Gomco suction machine (EQ235) to reflect the submitted invoices. Commenters stated that they supported the proposed transition in price increase for both pieces of equipment over the remaining 2 years of the pricing update and supported the ES031 price update to correctly account for the cost of the various components included in this scope video system.

Response: We appreciate the support for our proposals from the commenters.

Comment: A commenter stated that although they appreciated CMS's efforts to ensure the accuracy of the inputs for scope equipment, the price inputs for scope video systems do not capture all of the costs needed for near infrared fluorescence visualization with 4K monitors. The commenter stated that the actual cost of these processor, monitor, and digital capture device components are 45 to 97 percent higher than current CMS prices. The commenter encouraged CMS to seek additional price inputs for this newer technology and planned to submit invoices to demonstrate the costs related to the near infrared fluorescence scope video price inputs.

Response: We appreciate the feedback from the commenter regarding the costs associated with new technology being incorporated into scope video systems and we look forward to the submission of invoices or other data sources with additional pricing information. However, in the absence of information demonstrating these additional costs, we will continue to maintain our current scope pricing.

Comment: A commenter submitted invoices associated with three of the eight scope equipment items that still lacked a price: The cystoscopy rigid scope (ES070), the cystoscopy channeled flexible digital scope (ES081), and the hysteroscopy channeled flexible digital scope (ES082). The commenter stated that these invoices were representative of national pricing for these scopes and compiled a list of procedures associated with these scopes. This procedure list submitted by the commenter also included the hysteroscopy rigid scope, channeled (ES071) equipment item which was previously priced in CY 2020.

Response: We appreciate the additional pricing information submitted by the commenter in helping us assign a price to the remaining scope equipment codes. Based on this information, we are finalizing a price of $7,270.00 for the rigid scope, cystoscopy (ES070) equipment, a price of $22,274.36 for the channeled flexible digital scope, cystoscopy (ES081) equipment, and a price of $19,081.82 for the channeled flexible digital scope, hysteroscopy (ES082) equipment. When added to the previously finalized prices for the other scope equipment items from CY 2020, the total list is shown in Table 6.

TABLE 6: CY 2021 New Scope Equipment Codes

CMS Code	Scope Equipment Description	Finalized Price
ES070	rigid scope, cystoscopy	$7,270.00
ES071	rigid scope, channeled, hysteroscopy	$6,795.00
ES072	rigid scope, otoscopy	$2,333.98
ES073	rigid scope, nasal/sinus endoscopy	$3,004.75
ES074	rigid scope, proctosigmoidoscopy	
ES075	rigid scope, laryngoscopy	$3,966.08
ES076	rigid scope, colposcopy	$14,500.00
ES077	non-channeled flexible digital scope, hysteroscopy	
ES078	non-channeled flexible digital scope, nasopharyngoscopy	$21,923.43
ES079	non-channeled flexible digital scope, bronchoscopy	
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
ES081	channeled flexible digital scope, cystoscopy	$22,274.36
ES082	channeled flexible digital scope, hysteroscopy	$19,081.82
ES083	channeled flexible digital scope, bronchoscopy	
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
ES090	multi-channeled flexible digital scope, pouchoscopy	$17,360.00
ES091	ultrasound digital scope, endoscopic ultrasound	$0.00
ES092	non-video flexible scope, laryngoscopy	$5,105.97

With regard to the procedure list submitted by the commenter, we are not finalizing the replacement of any current scope equipment with the new scope equipment codes. We did not propose to make any such replacements in the proposed rule and we had reservations about some of the procedures on the submitted list, which included CPT codes that currently do not contain scopes or any direct PE inputs at all in some cases. We appreciate the submission of this additional information from the commenter and we will consider the procedure list for potential use in future rulemaking.

After consideration of the public comments, we are finalizing our proposal to update the price the ES031 scope video system equipment to $70,673.38 along with our proposed update to the price of the suction machine (Gomco) (EQ235) equipment. We are also finalizing the price for the three new scope equipment items as detailed above.

c. Technical Corrections to Direct PE Input Database and Supporting Files

For CY 2021, we proposed to address the following inconsistencies:

- Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and clarified that CPT code 0466T (Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator) is always performed on an add-on basis and would never be used as a standalone code. Therefore, we proposed to update the global period for CPT code 0466T to add-on status (ZZZ) to more accurately reflect the way in which this service is performed.

We received public comments on the technical corrections to direct PE input database and supporting files. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposed change to the global period of CPT code 0466T and agreed that this technical correction was appropriate.

Response: We appreciate the support for our proposal from the commenter.

Comment: Several commenters stated that in the direct PE inputs for CPT code 33202 (*Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)*), there are two tables listed under the equipment inputs: An exam table (EF023) and a power table (EF031). Commenters stated that spreadsheet information from CPT 2007 listed a power table and an exam light for this service, not an exam table. Commenters stated that it seemed likely that this was an accidental data entry error and requested that the equipment inputs for CPT code 33202 be corrected in the CMS equipment database to include a power table and exam light.

Response: We agree with the commenters that this was likely a data entry error confusing the exam light with the exam table. Based on the information supplied by the commenters, we are finalizing the replacement of the exam table with an exam light (EQ168) at the same equipment time of 36 minutes for CPT code 33202.

Comment: Several commenters stated that in the 2020 CMS direct PE inputs supplies listing, the ''unit'' type is missing for the skin prep barrier wipes (SM029) supply. Commenters stated that although this omission does not affect pricing, it makes it ambiguous what the units mean and could have an unintended impact if there are multiple different possible unit types, such as a liquid, where it would be unclear if it were ounces, milliliters, or something else. Commenters recommended that each supply item in the CMS database should have a unit type and provided a list of the supply items in the CY 2020 PFS final rule that were missing a unit type, with potential unit type suggestions for each item.

Response: We agree with the commenters that each supply item in the CMS database should include a unit type in order to avoid potential confusion regarding pricing. We are finalizing the addition of the unit types as listed in Table 7.

TABLE 7: Addition of Supply Unit Types

CMS Code	Description	Unit Type
SA115	hemorrhoidal banding system	item
SA116	continuous peripheral nerve block tray	tray
SA119	kit, low frequency ultrasound wound therapy (MIST)	kit
SA122	Claravein Kit	kit
SA123	Hysteroscopic fluid management tubing kit	kit
SC101	ultrasound needle	item
SC102	EBUS, single use aspiration needle, 21g	item
SC103	catheter, RF ablation, endoscopic	item
SD290	electrode, BIS (bioimpedance spectroscopy)	item
SD291	Urolift Implant and implantation device	item
SD292	10g IVAS drill	item
SD293	10g cannulae	item
SD294	Balloon for Bronchoscopy Fiberscope	item
SH106	CavityShield 5% Varnish .25mL	item
SJ089	ultrasound transmission gel, sterile (single use)	item
SK126	Beck Depression Inventory, Second Edition	item
SL519	Urethane Foaming Agent	item
SM029	skin prep barrier wipes	item

All of the supply items in the CMS database should now include a unit type with the additions from this list. We note that we did not add a unit type for the ''No Supplies'' (SX007) category as the commenter requested since this is not a supply item.

Comment: Several commenters questioned the proposed RVUs associated with several occupational therapy evaluation procedures (CPT codes 97165–97167). Commenters stated that the PE valuation for these codes appeared to be illogical, with the proposed valuation of the codes demonstrating an inverse relationship between PE value and complexity. Commenters stated that it was counterintuitive for the PE RVU to go down as the level of complexity increased. Commenters stated that the distribution of code usage has not changed in any manner to justify a reduction in the code values and that all three evaluation codes should reimburse at the same rate.

Response: We appreciate the commenters bringing this issue to our attention. However, although we agree with the commenters that the proposed valuation of these services is somewhat illogical, we do not agree that their proposed valuation represents a technical error. Although the three codes in question share the same work RVU and the same direct PE inputs, they do not share the same specialty distribution in the claims data and therefore will not necessarily receive the same allocation of indirect PE. In response to the comments, we are implementing a technical change which should ensure that these three services receive the same allocation of indirect PE.

Following the publication of the proposed rule, we also discovered a technical error in the published RVUs for three HCPCS codes. Code G0102 (*Prostate cancer screening; digital rectal examination*) was assigned the same value as CPT code 99211, the lowest level E/M service, in the CY 2000 PFS final rule (64 FR 59414). Code G0102 was assigned a work RVU of 0.17 which matched the work RVU of CPT code 99211 at the time. However, when we increased the work RVU for CPT code 99211 to 0.18 in CY 2010 as part of the last E/M revalution, the work RVU for HCPCS code G0102 was not increased to match. We are correcting this technical oversight by finalizing an increase in the work RVU of code G0102 from 0.17 to 0.18 to match the previously finalized crosswalk to CPT code 99211.

We also previously finalized and valued in the CY 1998 PFS final rule (62 FR 59082) the following two G codes for use when a barium enema is being substituted for either a screening sigmoidoscopy or screening colonoscopy: HCPCS codes G0106 (*Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema*) and G0120 (*Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema*). We established the same RVUs for these screening G codes as for the diagnostic barium enema procedure, CPT code 74280 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high density barium and air) study, including glucagon, when administered*). The work RVU for codes G0106 and G0120 has matched the work RVU for CPT code 74280 for the last two decades; however, we reviewed CPT code 74280 last year and, in the CY 2020 PFS final rule, increased the work RVU for CPT code 74280 to 1.26. Through an oversight, we did not make corresponding changes in the work RVUs for HCPCS codes G0106 and G0120. We are therefore correcting this technical oversight by finalizing an increase in the work RVU for HCPCS codes G0106 and G0120 to match the previously finalized crosswalk to CPT code 74280.

After consideration of the public comments, we are finalizing our proposals along with the additions as detailed above.

d. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2021, we proposed to update the price of one supply and four equipment items in response to the public submission of invoices. As these pricing updates were each part of the formal review for a code family, we proposed that the new pricing take effect for CY 2021 for these items instead of being phased in over 4 years. These supply and equipment items with updated prices associated with the formal review of a code family are listed in the valuation of specific codes section of the preamble under Table 31: CY 2021 Invoices Received for Existing Direct PE Inputs.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- The **Federal Register**, current DPEI data, historical proposed and final rules prior to CY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

(1) If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

(2) If no data were available for commercial products, the current CMS prices were used as the RP.

GSA prices were not used to calculate the StrategyGen recommended prices, due to our concern that the GSA system curtails the number and type of suppliers whose products may be accessed on the GSA Advantage website, and that the GSA prices may often be lower than prices that are available to non-governmental purchasers. After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicated that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties would experience increases or decreases in their Medicare payments if we were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, in the CY 2019 PFS proposed rule we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-

up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8.

TABLE 8: Example of Direct PE Pricing Transition

Current Price	$100	
Final Price	$200	
Year 1 (CY 2019) Price	$125	1/4 difference between $100 and $200
Year 2 (CY 2020) Price	$150	1/3 difference between $125 and $200
Year 3 (CY 2021) Price	$175	1/2 difference between $150 and $200
Final (CY 2022) Price	$200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer timeframe will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

We received many comments regarding the market-based supply and equipment pricing proposal following the publication of the CY 2019 PFS proposed rule. For a full discussion of these comments, we direct readers to the CY 2019 PFS final rule (83 FR 59475 through 59480). In each instance in which a commenter raised questions about the accuracy of a supply or equipment code's recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to ensuring that the recommended price was based on the correct item in question and the clarified unit of measure. Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. After consideration of the comments and this additional price research, we updated the recommended prices for approximately 70 supply and equipment codes identified by the commenters. Table 9 in the CY 2019 PFS final rule lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing (83 FR 59479 through 59480).

After consideration of the public comments, we finalized our proposals

associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the proposed updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2021, we received invoice submissions for approximately a dozen supply and equipment codes from stakeholders as part of the third year of the market-based supply and equipment pricing update. The submitted invoices were used in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. We reviewed the invoices, as well as prior data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. Based on this research, we proposed to update the prices of the supply and equipment items listed in Table 7 of the CY 2021 PFS proposed rule.

We finalized a policy in CY 2019 to phase in the new supply and equipment pricing over 4 years so that supply and equipment values transition smoothly from their current prices to the final updated prices in CY 2022. We finalized our proposal to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price was implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8. For CY 2021, one half of the difference between the CY 2020 price and the final price will be implemented as per the previously finalized policy. Table 9 contains the list of proposed CY 2021 market-based supply and equipment pricing updates:

TABLE 9: CY 2021 Proposed Market-Based Supply and Equipment Updates

CMS CODE	Description	CMS 2020 Price	Prior CMS 2022 Price	Prior CMS 2021 Price	Updated CMS 2022 Price	Updated CMS 2021 Price
SA105	UroVysion test kit	$153.040	$129.280	$141.160	$187.490	$170.265
SD089	guidewire, hydrophilic	$39.435	$43.370	$41.403	$13.350	$26.393
SD136	vascular sheath	$36.650	$52.800	$44.725	$24.444	$30.547
SD155	catheter, RF endovenous occlusion	$637.500	$550.000	$593.750	$382.500	$510.000
EQ041	Vmax 22d and 62j (PFT equip, autobox, computer system)	$47,930.000	$47,930.000	$47,930.000	$47,406.540	$47,668.270
ER044	nuclide rod source set	$1,783.167	$2,171.333	$1,977.250	$2,081.167	$1,932.167

The prices for the supply and equipment items listed in Table 9 were calculated based on averaging together the prices on the submitted invoices. In the case of the vascular sheath (SD136) and RF endovenous occlusion catheter (SD155) supplies, the price was determined by removing the sheath or catheter from the eight submitted kit invoices and then averaging the resulting price together with the single standalone sheath/catheter invoice.

In addition to submitting invoices with information updating the price of the ''Vmax 22d and 62j (PFT equip, autobox, computer system)'' (EQ041) equipment, stakeholders also clarified that the ''Vmax 229 (spirometry testing equip, computer system)'' (EQ040) and ''Vmax 29s (spirometry testing equip, computer system)'' (EQ043) equipment items have become obsolete and are no longer typically used in any HCPCS codes. Based on the information supplied by the stakeholders, we proposed to remove the EQ040 and EQ043 equipment items, replacing them with the EQ041 equipment at the same number of minutes in the six HCPCS codes where they are utilized.

We did not propose to update the price of additional supply and equipment items for which invoices were submitted following the publication of the CY 2020 PFS final rule. We did not propose to update the price for the ''pipette, transfer 23ml'' (SL109), ''slide specimen mailer (1–5 microscope slides)'' (SL121), ''stain, hematoxylin'' (SL135), ''stain, eosin'' (SL201), and ''stain, PAP OG–6'' (SL491) supplies. In each case we received a single invoice for these five supplies detailing price increases ranging from 82 percent to 160 percent above the current pricing. These supplies are commonly used in cytopathology procedures and we disagree that the typical price for these supplies has more than doubled since being reviewed by the StrategyGen contractor 2 years ago for CY 2019.

We also did not propose to update the price for the ''embedding mold'' (SL060) supply or the ''microscope, compound'' (EP060) equipment based on the same rationale. The submitted invoices represent pricing increases of 339 percent for the compound microscope and 7800 percent for the embedding mold and, based on the recent review of the pricing of these items by our contractor, we do not believe that the submitted invoices reflect typical market-based pricing. The same stakeholder also submitted an invoice to update the price of the surgical mask (SB033) supply by 617 percent over the current price. However, the invoice in question contains the price for a surgical mask with face shield, which is described by the SB034 supply code, not the SB033 supply code. Therefore, we did not propose to update the price of the surgical mask (SB033) supply based on this invoice. Finally, we received an invoice for a ClosureFast Procedure Pack (CFP) but it was unclear

what supply or equipment item this invoice was intended to update. As a result, we noted in the CY 2021 PFS proposed rule that we were unable to use this invoice to make a pricing proposal.

We received public comments on the market-based supply and equipment pricing update. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they continued to support the engagement from the agency to work with CMS contractors and stakeholders to incorporate current pricing data based on invoices into the calculation of direct PE cost. Commenters stated that bringing in an outside vendor in addition to accepting invoices from stakeholders was a reasonable approach, and that the incorporation of this new data and the process for determining what is accepted and what is rejected should be done in a transparent manner. Several different commenters urged CMS to be more deliberate and transparent about this decision-making process regarding supply and equipment pricing.

Response: We appreciate the feedback from the commenters and share the desire for transparency in pricing. We continue to believe that it is important to make use of the most current information available for supply and equipment pricing through the use of market-based research, and we agree with the need to explain the rationale behind the adoption or rejection of invoices submitted by stakeholders. We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. We consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Stakeholders are encouraged to submit invoices as part of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

Comment: A commenter stated that they supported the proposed pricing for the UroVysion test kit (SA105) supply. The commenter stated that establishing a price that is in line with invoice pricing ensures that reimbursement for the service reflects accurately the cost of resources involved in providing the service.

Response: We appreciate the support for our proposed pricing from the commenter.

Comment: A commenter disagreed with the proposed pricing of the lysing reagent (FACS) (SL089) supply. The commenter submitted six invoices for the supply and requested that CMS use them to update the pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SL089 supply. Therefore, we are finalizing an update in the price of this supply to $3.645 as indicated on the submitted invoices. As part of our ongoing pricing transition, the CY 2021 price of the supply will be $3.764 before reaching the finalized price of $3.645 in CY 2022.

Comment: One commenter disagreed with the proposed pricing of the radiofrequency introducer kit (SA026). The commenter stated that although some vendors now include this supply in an overall catheter pack, it is still common that many practices purchase this item separately. The commenter submitted two invoices for the supply and requested that CMS use them to update the pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SA026 supply. Therefore, we are finalizing an update in the price of this supply to $28.575 based on an average of the prices on the two submitted invoices. As part of our ongoing pricing transition, the CY 2021 price of the SA026 supply will be $32.83 before reaching the finalized price of $28.575 in CY 2022.

Comment: Several commenters disagreed with the proposed pricing of the hydrophilic guidewire (SD089) supply. Commenters stated that $27.76 would be a more appropriate reimbursement rate and submitted an invoice in support of their suggested pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SD089 supply. We noted that the guidewire on the newly submitted invoice was a different size than the guidewire on the invoice that we previously used for pricing the SD089 supply. Since we do not have information currently available as to which of these guidewires would be more typical, we are averaging together the two submitted invoices for a price of $20.555. As part of our ongoing pricing transition, the CY 2021 price of the SD089 supply will be $29.995 before reaching the finalized price of 20.555 in CY 2022.

Comment: A commenter disagreed with the proposed pricing of the endovascular laser treatment kit (SA074). The commenter stated that they were not sure that the proposed pricing was typical for the average clinic due to the economy of scale advantages available for larger providers. The commenter submitted three invoices for the supply and requested that CMS use them to update the pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SA074 supply. The unit prices on the three submitted invoices were $431.08 (for a pack of five), $438.60 (for a pack of two), and $535.60 for an individual supply. The price for the individual endovascular laser treatment kit was significantly higher than the other invoice prices and we believe that this price would not be typical in light of the other pricing data that we have available. Therefore, we are finalizing an update in the price of this supply to $438.60 based on taking the median of the submitted invoices which we believe to be more representative of typical pricing. As part of our ongoing pricing transition, the CY 2021 price of the SA074 supply will be $429.88 before reaching the finalized price of $438.60 in CY 2022.

Comment: A commenter disagreed with the proposed pricing of the tubing set (Liposorber) (SC083) and plasma separator (Liposorber) (SD188) supplies. The commenter stated that the proposed prices did not accurately reflect the actual average prices paid by their U.S. provider customers. The commenter submitted 45 invoices for the two supplies and requested that CMS use them to update the pricing.

Response: We appreciate the submission of this large quantity of additional invoices for use in pricing the SC083 and SD188 supplies. After reviewing the invoices, we agree with the commenter that the average sales price matches the numbers listed in their comment letter. Therefore, we are finalizing an update in the price of the SC083 supply to $75.71 and an update in the price of the SD188 supply to $131.42 as indicated on the submitted invoices. As part of our ongoing pricing transition, the CY 2021 price of the SC083 supply will be $62.28 and the CY 2021 price of the SD188 supply will be $113.04 before reaching their finalized prices in CY 2022.

Comment: Several commenters disagreed with the proposed pricing for the RF endovenous ablation catheter (SD 155) and the vascular sheath (SD 136) supplies. Commenters stated that the proposed prices did not reflect the reality of their practice's economics and expressed concern that such reductions could encourage office-based physicians to curtail or cease performing these

procedures. Commenters stated that the proposed pricing for RF catheters and sheaths represented the price being paid by high-volume or large multi-location practices and did not reflect the prices paid by smaller providers who are more typical. Due to the greater negotiating power and high volume discounts available to larger practices, commenters stated that the proposed supply pricing did not seem be to what typical providers pay and that the current pricing of $52.80 was more representative for the vascular sheath. One commenter requested a more thorough review of the data CMS used to determine the updated pricing for the SD136 and SD155 supplies as well as the opportunity to provide additional data to validate their pricing. Several commenters submitted a series of invoices for the RF endovenous occlusion catheter (SD155) that they stated were more typical of pricing and urged CMS to update the supply pricing accordingly.

Response: We appreciate the additional information provided by the commenters regarding the pricing of these supplies, especially the invoices with additional pricing data for the SD155 catheter. The commenters are correct that the proposed pricing for the SD155 supply was based in part on a bulk order and that ordering the catheters on an individual basis resulted in higher prices. However, we do not agree that it would be accurate to base the pricing of the SD155 supply solely on the basis of individual orders with no discounts included, as it is clear from the submitted invoices that there exists a variety of discounts available for providers. Therefore, we are averaging together the newly submitted invoices together with our previous invoices for the SD155 supply and finalizing the resulting price of $487.92. As part of our ongoing pricing transition, the CY 2021 price of the supply will be $562.71 before reaching the finalized price of $487.92 in CY 2022.

We did not receive any invoices with updated pricing information for the vascular sheath (SD136) supply. In the absence of additional information, we believe that the proposed price for the vascular sheath accurately reflects the cost of this supply and we are finalizing the proposed price of $24.44. We continue to welcome the submission of invoices with additional information regarding the pricing of these two or any other supply items.

Comment: Several commenters stated that they believe the HDR Afterload System, Nucletron—Oldelft (ER003) and the SRS System, SBRT, Six Systems (ER083) equipment items remain significantly undervalued relative to fair market pricing. The commenters stated that it was imperative for CMS equipment pricing to accurately reflect marketplace pricing given the high cost of these items and their substantial utilization in certain radiation oncology delivery codes. One commenter stated that the pricing for this equipment may represent a less costly electronic brachytherapy system used to treat skin cancer or an equipment upgrade or refurbished equipment. The commenters requested that CMS conduct additional research regarding fair and accurate market pricing for these two equipment items and accept newly submitted invoices during the 60-day comment period. One commenter requested a one-year moratorium on phasing in the StrategyGen revised pricing inputs and maintain all direct PE inputs at 2020 levels.

Response: We share the desire of the commenter for fair and accurate market-based pricing for these two equipment items. However, both of these equipment items were priced based on research conducted by our StrategyGen contractor and then were updated in response to additional information supplied by commenters in the CY 2019 PFS final rule (83 FR 59478–59479). In the absence of additional information, we believe that the current prices accurately reflect the cost of these equipment items. We continue to welcome the submission of invoices with additional information regarding the pricing of these two or any other equipment items. We also note that the ongoing market-based supply and equipment pricing update was previously finalized in CY 2019 rulemaking and we do not agree that a one-year moratorium on the continuing pricing transition would facilitate our goal of ensuring current pricing.

After consideration of the public comments, we are finalizing our proposals associated with the market-based supply and equipment pricing update as detailed above. Table 10 contains the list of finalized CY 2021 market-based supply and equipment pricing updates:

TABLE 10: CY 2021 Finalized Market-Based Supply and Equipment Updates

CMS CODE	Description	CMS 2020 Price	Prior CMS 2022 Price	Prior CMS 2021 Price	Updated CMS 2022 Price	Updated CMS 2021 Price
SA026	kit, radiofrequency introducer	$37.080	$24.160	$30.620	$28.575	$32.828
SA074	kit, endovascular laser treatment	$421.165	$323.330	$372.248	$438.600	$429.883
SA105	UroVysion test kit	$153.040	$129.280	$141.160	$187.490	$170.265
SC083	tubing set (Liposorber)	$48.840	$47.680	$48.260	$75.710	$62.275
SD089	guidewire, hydrophilic	$39.435	$13.350	$26.393	$20.555	$29.995
SD136	vascular sheath	$36.650	$52.800	$44.725	$24.444	$30.547
SD155	catheter, RF endovenous occlusion	$637.500	$382.500	$510.000	$487.920	$562.710
SD188	plasma separator (Liposorber)	$94.660	$89.320	$91.990	$131.420	$113.040
SL089	lysing reagent (FACS)	$3.883	$3.280	$3.581	$3.645	$3.764
EQ041	Vmax 22d and 62j (PFT equip, autobox, computer system)	$47,930.000	$47,930.000	$47,930.000	$47,406.540	$47,668.270
ER044	nuclide rod source set	$1,783.167	$2,171.333	$1,977.250	$2,081.167	$1,932.167

(2) Invoice Submission

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Stakeholders are encouraged to submit invoices as part of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

(3) Updated Supply Pricing for Venous and Arterial Stenting Services

Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and presented additional information regarding supply pricing for certain venous and arterial stenting services. These stakeholders stated that the use of the ''stent, vascular, deployment system, Cordis SMART'' (SA103) supply was no longer typical in CPT codes 37238 (*Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein*) and 37239 (*Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein*). The stakeholders stated that a new venous stent system had become the typical standard of care for these services, and they supplied ten invoices for use in pricing this supply.

The stakeholders also requested additional information regarding the nature of the ''stent, balloon, implantable'' (SD299) supply included in CPT codes 37236 (*Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery*) and 37237 (*Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery*). The stakeholders specifically were unclear what the implantable stent balloon represented and sought guidance on whether pricing involved a stent, a balloon, or a combination of both.

In response to the additional information provided by the stakeholders, we proposed to remove the SA103 supply item from CPT codes 37238 and 37239. We proposed to replace it with a newly created ''venous stent system'' (SD340) supply at the same supply quantity. We proposed a price of $1,750.00 for the venous stent system based on the median price of the ten invoices supplied by the stakeholders. We proposed the use of the median price due to the presence of several invoices that appear to be outliers, which are not reflective of

market pricing for the venous stent system. With regards to the request for additional information regarding the nature of the ''stent, balloon, implantable'' (SD299) supply, the original invoice used to price this supply during the CY 2015 rule cycle listed an item named ''Renal and Biliary Stent System 7.0 mm × 15 mm × 135 cm''. We welcomed additional information from stakeholders regarding the nature and pricing of this supply item.

We received public comments on our proposals associated with updated supply pricing for venous and arterial stenting services. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported the proposed change to replace the stent for CPT codes 37238 and 37239. One commenter stated that they appreciated the additional information on the two CPT codes and looked forward to researching this issue further.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing our proposals associated with updated supply pricing for venous and arterial stenting services.

(4) Myocardial PET Equipment Inputs

Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and presented additional information regarding the direct PE inputs for several codes associated with Myocardial PET services. The stakeholders stated that the nuclide rod source set (ER044) equipment was inadvertently excluded from the direct PE recommendations for CPT codes 78432 (*Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability)*), 78459 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study)*), 78491 (*Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)*), and 78492 (*Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)*), and requested that CMS add this equipment to the direct inputs for this group of CPT codes. The stakeholders also stated that the current useful life of 5 years for the ER044 equipment was incorrect as these sources are replaced every 9 months to 1 year. The stakeholders requested that CMS update the useful life of ER044 to 0.75 years. Finally, the stakeholders stated that the costs for the purchase of the Rubidium PET Generator (ER114) equipment are captured elsewhere through the billing of HCPCS supply code A9555, and the stakeholders recommended that we remove equipment item ER114 to avoid incorrect billing duplication.

We noted that we appreciate the additional information submitted by the stakeholders regarding the direct PE inputs for these Myocardial PET services. In response to this new information, we proposed to update the price for the nuclide rod source set (ER044) equipment to $2,081.17 based on averaging together the price of the three submitted invoices after removing the shipping and delivery costs according to our standard pricing methodology. We also proposed to add the ER044 equipment to CPT codes 78432, 78459, 78491, and 78492 as requested, assigning the same equipment time utilized by the ''PET Refurbished Imaging Cardiac Configuration'' (ER110) equipment in each service. We proposed to update the useful life of the ER044 equipment to one year in accordance with our proposed policy to treat equipment useful life durations of less than 1 year as having a duration of one year. As we stated previously in section II.B, we have concerns that assigning very low useful life durations of less than 1 year would fail to maintain relativity with other equipment on the PFS, and the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. We direct readers to the previous discussion regarding equipment cost per minute methodology earlier in section II.B. of this final rule. Finally, we are removing the ''PET Generator (Rubidium)'' (ER114) equipment from our database as requested by the stakeholders. We noted that since the technical components for CPT codes 78432, 78459, 78491, and 78492 are all contractor-priced, there will be no change to the national pricing of these codes.

We received public comments on our proposals associated with Myocardial PET equipment inputs. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they agreed with and supported all four of the CMS proposals associated with Myocardial PET equipment inputs. Commenters also stated that they supported the decision to maintain contractor pricing for the technical components for all the new and revised Myocardial PET codes. Commenters stated that the standard CMS formula and RUC PE inputs do not allow for certain high-cost expenses that are generally part of overhead to be factored into the RVUs and requested that contractor pricing continue to be maintained for these services.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing our proposals associated with Myocardial PET equipment inputs.

(5) Autologous Platelet-Rich Plasma (HCPCS Code G0460) Supply Inputs

We did not make any proposals associated with HCPCS code G0460 (*Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment*) in the CY 2021 PFS proposed rule. Following the publication of the rule, stakeholders contacted CMS regarding the creation of a new 3C patch system supply which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds. Stakeholders first sought clarification on how CMS calculated the underlying nonfacility PE RVUs for HCPCS code G0460. Stakeholders also stated that autologous platelet rich plasma administration procedures furnished in clinical trials (including the new 3C patch system) are reported using HCPCS code G0460 and requested that CMS revalue the service to reflect the PEs associated with the new patch system supply. The stakeholders stated that the use of the new 3C patch system will represent the typical case for HCPCS code G0460 and the therefore the cost inputs for this supply should be used to establish the RVUs for this code as the current MPFS rate is substantially less than the amount it costs to furnish the 3C patch.

We clarify for stakeholders that the valuation of the direct PE inputs increased for HCPCS code G0460 as a result of the ongoing market-based supply and equipment pricing update. However, there was also a minor

decrease in the indirect PE allocation associated with this service, with the net result that the proposed PE RVU coincidentally ended up remaining the same as in the previous year. We also clarify for stakeholders that HCPCS code G0460 is not included in the Anticipated Specialty Assignment for Low Volume Services list, and therefore, was unaffected by low utilization in the claims data.

We understand that the stakeholders originally believed that the new 3C patch system would be reported using new HCPCS coding before CMS issued a clarification that the clinical trials associated with this supply would be reported under HCPCS code G0460. We share the concerns of the stakeholders that patient access to the 3C patch will be materially impacted if CMS maintains reimbursement for HCPCS G0460 at the current rate. However, we note that we did not propose to increase the price of HCPCS code G0460 in the PFS proposed rule, and we have concerns about finalizing a fivefold increase in the pricing of this service without going through notice and comment rulemaking. Therefore, we are finalizing contractor pricing for HCPCS code G0460 for CY 2021 to allow for increased pricing for this service when it includes the 3C patch system without establishing a new national price. We believe that the use of contractor pricing will allow additional time to determine the most accurate pricing for HCPCS code G0460. We are also adding the 3C patch system to our supply database under supply code SD343 at a price of $625.00 based on an average of the submitted invoices.

(6) Adjustment to Allocation of Indirect PE for Some Office-Based Services

In the CY 2018 PFS final rule (82 FR 52999 through 53000), we established criteria for identifying the services most affected by the indirect PE allocation anomaly that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. We also finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services. The methodology, as described, is based on the difference between the ratio of indirect PE to work RVUs for each of the codes meeting eligibility criteria and the ratio of indirect PE to work RVU for the most commonly reported visit code. We refer readers to the CY 2018 PFS final rule (82 FR 52999 through 53000) for a discussion of our process for selecting services subject to the revised methodology, as well as a description of the methodology, which we began implementing for CY 2018 as the first year of a 4-year transition.

For CY 2021, we proposed to continue with the fourth and final year of the transition of this adjustment to the standard process for allocating indirect PE.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

e. Update on Technical Expert Panel Related to Practice Expense

The RAND Corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it. As we noted earlier in this section, our current system for setting PE RVUs relies in part on data collected in the Physician Practice Information Survey (PPIS), which was administered by the AMA in CY 2007 and 2008.

RAND, in its first phase of research, available at *https://www.rand.org/pubs/research_reports/RR2166.html*, found that the PPIS data are outdated and may no longer reflect the resource allocation, staffing arrangements, and cost structures that describe practitioners' resource requirements in furnishing services to Medicare beneficiaries, and consequently may not accurately capture the indirect PE resources required to furnish services to Medicare FFS beneficiaries. For example, the PPIS preceded the widespread adoption of electronic health records, quality reporting programs, billing codes that promote team-based care, and hospital acquisition of physician practices. Notably, RAND found that practice ownership was strongly associated with indirect PE, with physician-owned practices requiring 190% higher indirect PE compared to facility-owned practices, suggesting a need to potentially update demographic information. Additionally, RAND found that aggregating Medicare provider specialties into broader categories resulted in small specialty-level impacts relative to the current system, suggesting that specialty-specific inputs may not be required to accurately reflect resource costs.

To follow up on these and other issues raised in the first phase of RAND's research, in the CY 2020 PFS, we announced that RAND was convening a technical expert panel (TEP) to obtain input from stakeholders including physicians, practice and health system managers, health care accountants, and health policy experts. The TEP occurred on January 10, 2020 and its report is available at *https://www.rand.org/pubs/working_papers/WR1334.html*. Topics discussed included identifying issues with the current system; changes in medicine that have affected PE; how PE inputs could be updated, including through a potential new survey instrument; how best to aggregate PE categories if there were to be new survey instrument; ways to maximize response rates in a potential new survey; and using existing data to inform PFS PE rates. In addition, RAND has issued the results of its subsequent phase of research, available at *www.rand.org/t/RR3248*. This report is also available as a public use file displayed on the CMS website under downloads for the CY 2021 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Based on the results of the TEP and RAND's other ongoing research, we are interested in potentially refining the PE methodology and updating the data used to make payments under the PFS. We believe that potential refinements could improve payment accuracy and strengthen Medicare. Our goals are to balance obtaining the data as soon as practicable and in a way that would allow stakeholders and CMS to collectively examine many of the issues the TEP and RAND's research identified. We noted that we were considering several questions, including how to best incorporate market-based information, which could be similar to the market research that we recently conducted to update supply and equipment pricing used to determine direct PE inputs under the PFS payment methodology. For example, stakeholders have expressed an interest in updating the clinical labor data that we use for direct PE inputs based on current salaries and compensation for the health care workforce. We solicited comment regarding how we might update the clinical labor data. We noted that historically we have used data from the Bureau of Labor Statistics and sought comment to determine if this is the best data source or if there is an alternative. We also noted that we are interested in hosting a Town Hall meeting at a date to be determined to provide an open forum for discussion with stakeholders on our ongoing research to potentially update the PE methodology and the underlying inputs. Finally, we welcomed feedback from all interested parties regarding RAND's report and clarified that we were not making any proposals based on this report for this rulemaking cycle We encouraged stakeholders to submit feedback as part

of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

We received public comments on the update on technical expert panel related to PE. The following is a summary of the comments we received and our responses.

Comment: In response to the RAND report, commenters encouraged CMS to work with stakeholders on any new PE data collection effort.

Response: We agree that we would want to engage with stakeholders as part of any new PE data collection effort. Our public notice and comment rulemaking process is the venue we would use for any potential future proposals.

Comment: Commenters were supportive of CMS convening a Town Hall meeting.

Response: We appreciate and are encouraged by commenters' support. We continue to believe that a Town Hall would provide open forum for discussions with stakeholders. We remain interested in hosting this meeting at a date to be determined.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.H. of this final rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to

facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well. Individuals and stakeholder groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox *Medicare PhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes''. Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; final rule (76 FR 73052 through 73055) (hereinafter referred to as the ''CY 2012 PFS final rule with comment period''). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 FR 68892) (hereinafter referred to as the ''CY 2013 PFS final rule with comment period''), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (73 FR 38589) (hereinafter referred to as the ''CY 2009 PFS proposed rule''), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2021 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and

organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

We received submissions nominating codes for review under the potentially misvalued code initiative, and several requests for review of PE related inputs prior to our February 10, 2020 deadline. We refer readers to section II.B. of this final rule, Determination of Practice Expense RVUs, for further discussion on the PE-related submissions. The summary of the submissions reviewed under the potentially misvalued code initiative is discussed below.

We received multiple submissions requesting that CMS consider CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*) for nomination as potentially misvalued. In their request, the submitters suggested that the physician work assigned to this code significantly undervalues the procedure relative to the value of CPT code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar*). The submitters stated that the work performed during the surgical steps to perform a laminectomy for both procedures is generally similar except for the additional intensity and complexity involved in CPT code 22867 to implant the interspinous stabilization device. The submitters also requested that the malpractice RVUs assigned to this code be increased to better align with similar spine procedures, in terms of specialty-level and service-level risk factors, in addition to the intensity and complexity of the procedure. After considering the information provided by the submitter, which suggests that the current valuation for the service may not reflect the level of intensity inherent in furnishing the service relative to other similar services with inputs that exceed those for the nominated service, we proposed to nominate CPT code 22867 as potentially misvalued and welcomed public comment on this code.

We received public comments on the CY 2021 identification and review of potentially misvalued services. The following is a summary of the comments we received and our responses.

Comment: The AMA RUC has indicated that CPT code 22867 will be placed on a list they call the ''next Level of Interest for review.''

Response: We acknowledge and thank the AMA RUC's placement of CPT code 22867 on their ''next Level of Interest for review'' list and look forward to their input, as well as input from the initial submitters of CPT code 22867 and all other parties.

Comment: Some commenters expressed support for the nomination of CPT code 22867 as a potentially misvalued code, but disagreed with the comparison to CPT code 63047. Some commenters stated that CPT code 22867 was misvalued from its last review in 2016, when CMS determined a work RVU of 13.50 over the AMA RUC recommended work RVU of 15.00. Commenters stated that CMS already has the necessary survey data from the specialties who perform this service—which had been surveyed and reviewed twice by the AMA RUC with the same outcome, and that the procedure's technology has not changed since the last survey. One commenter also highlighted differences between CPT code 63047 and CPT code 22867, noting that CPT code 63047 involves more postoperative work (as an inpatient service), spends more time with intense imaging services and device sizing, and that the decompression performed is more extensive than CPT code 22867, all of which supports the relative greater RVU amount for CPT code 63047.

Response: We acknowledge and appreciate comments and feedback from CPT code 22867 stakeholders who have expressed their reasons both for and against the nomination of this code as potentially misvalued.

Comment: Some commenters requested that CMS nominate HCPCS codes G0442 (*Annual alcohol misuse screening, 15 minutes*) and G0444 (*Annual depression screening, 15 minutes*) as potentially misvalued due to the possible misinterpretation of their descriptors. These commenters highlighted that the descriptors may appear to convey that the physician providing the service must provide a full 15 minutes of screening to report either of these services. The commenters stated their understanding of the descriptor to mean ''up to 15 minutes'' to perform the screenings, and suggested that CMS adjust the official descriptors to say G0442 (*Annual alcohol misuse screening, up to 15 minutes*) and G0444 (*Annual depression screening, up to 15 minutes*), and for CMS to provide an educational announcement to clarify the proposed change.

Response: We thank the commenters for these suggestions for clarifications on HCPCS codes G0442 and G0444 descriptors and welcome comments and continued engagement with stakeholders on all aspects of coding that improves accuracy and promotes clarity.

Comment: Several commenters nominated CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) as being potentially misvalued, due to the PFS presently only making payment for this service in the facility setting and not in the office setting. Commenters requested that CMS review this code, and value the required resources for correct payment in the office setting. They contend that the procedure can be performed in the office, just as safely as it is done in an ASC or outpatient setting, and that it might be a more convenient site of service for the physician and for the patient. CPT code 49436 helps promote home peritoneal dialysis, which falls in line with the President's Executive Order (E.O.) on Advancing American Kidney Health and keeps patients at home during the PHE for COVID–19 rather than having to travel to a dialysis center three times a week.

Response: While CMS had decided not to nominate CPT code 49436 in the proposed rule as being potentially misvalued, commenters resubmitted their nomination during this comment period. We appreciate all of the comments and feedback that we have received for nominating CPT code 49436 as potentially misvalued and further to consider valuing CPT code 49436 in the office setting. We intend to research the information provided and understand more about the potential impact of valuing CPT code 49436 in the office setting and may consider for future rulemaking.

Comment: Commenters referenced codes that were publicly nominated in CY 2019 as misvalued by a national commercial insurer. The commenter expressed disappointment that CMS accepted these public nominations from a private national commercial insurer, as they could potentially represent a possible conflict of interest in their role

as a private commercial medical insurance and Medicare Advantage payer to the providers of physician services. The commenter urged CMS to evaluate how it considers public nominations from parties with possible conflicts in payment determinations.

Response: CMS will accept and review all public nomination of services that may be potentially misvalued, as appropriate. As we had stated in our CY 2019 PFS final rule, we also reiterate that we continue to be open to reviewing additional and supplemental sources of data furnished by stakeholders, and providing such information to CMS is not limited to the public nomination process for potentially misvalued codes. We encourage stakeholders to continue to provide such information for our consideration, as this information may support CMS' review and refinement of work RVUs that are the basis for payment for many services under the PFS.

Comment: One commenter urged CMS to use its authority to adjust CY 2018 Medicare payments for physicians' services to increase the current rate for managing home patients (CPT code 90966 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older*) 6.77 RVU) and to the maximum payment amount for managing in-center patients (CPT code 90960 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month*) 8.07 RVU); however, no supporting documentation was included with this nomination request.

Response: Should there be compelling evidence of substantial change in the nature of CPT codes 90966 and 90960 and their relationship to each other since their 2018 review, the commenter is free to nominate these codes as potentially misvalued and lend support and evidence to that effect for the next proposed rule.

After consideration of the public comments, we are finalizing our proposal to nominate CPT code 22867 as potentially misvalued. We appreciate all of the comments and information we have received from stakeholders about services that they believe to be potentially misvalued and look forward to receiving new and additional information prior to our February 10th deadline for our next round of rulemaking.

D. Telehealth and Other Services Involving Communications Technology, and Interim Final Rule With Comment Period for Coding and Payment of Virtual Check-In Services

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in the CY 2021 PFS proposed rule (85 FR 50095) and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, see the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and in 42 CFR 410.78 and 414.65.

a. Adding Services to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare telehealth services list in accordance with section 1834(m)(4)(F)(ii) of the Act (§ 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare telehealth services list to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare telehealth services list. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The Medicare telehealth services list, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

For CY 2021, requests to add services to the Medicare telehealth services list must have been submitted and received by February 10, 2020. Each request to add a service to the Medicare telehealth services list must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare telehealth services list, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare telehealth services list, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2021

Under our current policy, we add services to the Medicare telehealth services list on a Category 1 basis when we determine that they are similar to

services on the existing Medicare telehealth services list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the Medicare telehealth services list that resemble those services already on the Medicare telehealth services list. We received several requests to add various services as Medicare telehealth services effective for CY 2021. We also conducted an internal review of potential services to add to the Medicare telehealth services list.

In response to the public health emergency (PHE) for Coronavirus Disease 2019 (COVID–19), CMS undertook emergency rulemaking to add a number of services to the Medicare telehealth services list on an interim final basis. In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (IFC), (which was issued on March 31, 2020 and appeared in the April 6, 2020 **Federal Register** (85 FR 19230, 19234 through 19241) (hereinafter referred to as the ''March 31st COVID–19 IFC''), on an interim final basis for the duration of the PHE for COVID–19, we also finalized the addition of a number of services to the Medicare telehealth services list on a Category 2 basis. The following is a list of those services:

- Emergency Department (ED) Visits, Levels 1–5 (CPT codes 99281–99285).
- Initial and Subsequent Observation and Observation Discharge Day Management (CPT codes 99217–99220; CPT codes 99224–99226; CPT codes 99234–99236).
- Initial Hospital Care and Hospital Discharge Day Management (CPT codes 99221–99223; CPT codes 99238–99239).
- Initial nursing facility visits, All levels (Low, Moderate, and High Complexity) and nursing facility discharge day management (CPT codes 99304–99306; CPT codes 99315–99316).
- Critical Care Services (CPT codes 99291–99292).
- Domiciliary, Rest Home, or Custodial Care services, New and Established patients (CPT codes 99327–99328; CPT codes 99334–99337).
- Home Visits, New and Established Patient, All levels (CPT codes 99341–99345; CPT codes 99347–99350).
- Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT codes 99468–99472; CPT codes 99475–99476).
- Initial and Continuing Intensive Care Services (CPT code 99477–994780).
- Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483).
- Group Psychotherapy (CPT code 90853).
- End-Stage Renal Disease (ESRD) Services (CPT codes 90952, 90953, 90959, and 90962).
- Psychological and Neuropsychological Testing (CPT codes 96130–96133; CPT codes 96136–96139).
- Therapy Services, Physical and Occupational Therapy, All levels (CPT codes 97161–97168; CPT codes 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521–92524, 92507).
- Radiation Treatment Management Services (CPT codes 77427).

When we previously considered adding these services to the Medicare telehealth services list, either through a public request or through our own internal review, we considered whether these services met the Category 1 or Category 2 criteria. In many cases, we reviewed requests to add these services on a Category 1 basis, but did not receive or identify information that allowed us to review the services on a Category 2 basis. While we stated in the March 31st COVID–19 IFC that we did not believe the context of the PHE for COVID–19 would change the assessment of these services as Category 1, we did reassess all of these services on a Category 2 basis in the context of the widespread presence of COVID–19 in the community.

Given the exposure risks for beneficiaries, the health care work force, and the community at large, we stated that in-person interactions between professionals and patients posed an immediate potential risk that would not have been present when we previously reviewed these services. We were concerned that this new risk created a unique circumstance where health care professionals might have to choose between mitigating exposure risk for themselves and for their patients or seeking Medicare payment for the service. For example, certain persons, especially older adults who are particularly vulnerable to complications from this specific viral infection; those considered at risk because of underlying health conditions; and those known to be recently exposed or diagnosed, and therefore, likely to spread the virus to others, were often being directed by local public health officials to self-isolate as much as possible. At the same time, we noted that the risk to medical professionals treating patients is high and we considered it likely that medical professionals would try to treat patients as effectively as possible without exposing themselves or their patients unnecessarily. We explained that, in some cases, the use of telecommunications technology could mitigate the exposure risk; and in such cases, there is a clear clinical benefit of using such technology in furnishing the service. In other words, patients who should not be seen by a professional in-person due to the exposure risk were highly likely to be without access to clinically appropriate treatment or diagnostic options unless they have access to services furnished through interactive communication technology.

Therefore, in the context of the PHE for COVID–19, we believed that all of the services we added met the Category 2 criteria to be added to the Medicare telehealth services list on the basis that there was a patient population that would otherwise not have access to clinically appropriate treatment. We noted that, as with other services on the Medicare telehealth services list, it may not be clinically appropriate or possible to use telecommunications technology to furnish these particular services to every person or in every circumstance. In the context of the PHE for COVID–19, with specific regard to the exposure risks noted above, we recognized the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure.

The following presents a discussion of these services and the related proposals.

After reviewing the requests we received and the services we identified for consideration, we identified the services listed in Table 11 as being sufficiently similar to services currently on the Medicare telehealth services list to be added on a Category 1 basis. Therefore, we proposed to add the services in Table 11 to the Medicare telehealth services list on a Category 1 basis for CY 2021.

TABLE 11: CY 2021 Proposed and Final Additions to the Medicare Telehealth Services List on a Category 1 Basis

HCPCS Code	Long Descriptor
G2211	Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)
90853	Group psychotherapy (other than of a multiple-family group)
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [e.g., acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
G2212	Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (e.g., basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (e.g., functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (e.g., home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.
99334	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.
99335	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.
99347	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.

HCPCS Code	Long Descriptor
99348	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.

We noted that we believe the services described by the HCPCS codes in Table 11 are similar to services currently on the Medicare telehealth services list. The HCPCS codes G2211 and G2212 are add-on codes to the office/outpatient evaluation and management (O/O E/M) services and are, by definition, part of the O/O E/M services with which they are billed; they cannot be billed with any other codes. These codes were previously described by placeholder HCPCS codes GPC1X and 99XXX (for G2211 and G2212, respectively). For further discussion of these codes, please see section II.F.2.c of this rule. The Assessment of and Care Planning for Patients with Cognitive Impairment was defined as a service meant to be billed in specific clinical scenarios in lieu of a level 5 O/O E/M visit. As such, these services fall within the Category 1 criteria, because they are similar to the office visits that are already on the Medicare telehealth services list. As it describes group therapy, CPT code 90853 is similar to the other group therapy services currently on the Medicare telehealth services list.

While the patient's home cannot serve as an originating site (where the patient is located) for purposes of most Medicare telehealth services, the SUPPORT for Patients and Communities Act amended section 1834(m)(4)(C) of the Act and added a new paragraph at section 1834(m)(7) of the Act to remove geographic limitations and authorize the patient's home to serve as a telehealth originating site for purposes of treatment of a substance use disorder (SUD) or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a SUD diagnosis. These domiciliary/home visits contain the same elements and similar descriptors to the O/O E/M visits, and therefore, we noted that there is sufficient justification to add them to the Medicare telehealth services list on a Category 1 basis. Additionally, we noted that, due to the vulnerability of this particular patient population that are receiving treatment for a diagnosed SUD or co-occurring mental health disorder, we should maximize the availability of telehealth services for the treatment of SUDs and co-occurring mental health disorders. We also noted that, because the home is not generally a permissible telehealth originating site, these services could be billed when furnished as telehealth services only for treatment of a SUD or co-occurring mental health disorder.

Finally, we received a request to add CPT code 96121 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [e.g., acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)*) on the basis that this is an add-on code to CPT code 96116 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [e.g., acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour*), which is currently on the Medicare telehealth services list. In the past, we have added services to the Medicare telehealth services list that are add-on codes that describe a continuation or additional elements of services currently on the Medicare telehealth services list since the services would only be considered telehealth services when billed as an add-on to codes already on the Medicare telehealth services list (82 FR 53008). Therefore, we proposed to add CPT code 96121 to the Medicare telehealth services list.

We also received a request to add services to the Medicare telehealth services list that do not meet our criteria for addition to the Medicare telehealth services list. We did not propose to add the services listed in Table 12 to the Medicare telehealth services list.

TABLE 12: Services Requested for Addition to the Medicare Telehealth Services List Not Proposed for Addition

Service Type	HCPCS	Long Descriptor
Medical Genetics	96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family
	S0265	Genetic counseling, under physician supervision, each 15 minutes

We received a request to add Medical Genetics services to the Medicare telehealth services list. We note that CPT code 96040 is considered bundled into O/O E/M visits, which are already on the Medicare telehealth services list. Therefore, we do not believe it is necessary to add CPT code 96040. As we stated in the CY 2012 PFS final rule

with comment period (76 FR 73096 through 73097), physicians and NPPs who may independently bill Medicare for their services and who are counseling individuals would generally report office or other outpatient E/M CPT codes for office visits that involve significant counseling, including genetic counseling, and these office visit CPT codes are already on the Medicare telehealth services list. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. Genetic counselors are not among the practitioners who can bill Medicare directly for their professional services, and they are also not practitioners who can furnish telehealth services as specified in section 1834(m)(4)(E) of the Act. As such, we noted that we do not believe that it would be necessary or appropriate to add CPT code 96040 to the Medicare telehealth services list.

HCPCS code S0265 is a Medication, Supplies, and Services code. There is no separate payment under the PFS for this category of codes. Therefore, we did not propose to add this service to the Medicare telehealth services list.

We received public comments on the requests to add services to the Medicare telehealth services list for CY 2021. The following is a summary of the comments we received and our responses.

Comment: Commenters broadly supported our proposal to add HCPCS codes and CPT codes 90853, 96121, G2212, 99483, 99334, 99335, 99347, and 99348 to the Medicare telehealth list on a Category 1 basis.

Response: We thank the commenters for their support and feedback.

Comment: One commenter opposed the addition of G2211 to the Medicare telehealth list on the basis they do not agree the creation of the code.

Response: We thank the commenter for their feedback and refer them to section II.F.2.c. of this final rule for further discussion of payment policies for HCPCS code G2211. We note that HCPCS codes G2211 and G2212 replace GPC1X and 99XXX respectively, please see section II.F.2.c in this final rule.

Comment: One commenter requested clarification on the addition of CPT codes 99347 and 99348 (*Home visit for the evaluation and management of an established patient*). Specifically, the commenter requested clarification from CMS on the situations in which a home visit after the end of the PHE for COVID–19 would be allowed via telehealth.

Response: While the patient's home cannot serve as an originating site (where the patient is located) for purposes of most Medicare telehealth services, the SUPPORT for Patients and Communities Act amended section 1834(m)(4)(C) of the Act and added a new paragraph at section 1834(m)(7) of the Act to remove geographic limitations and authorize the patient's home to serve as a telehealth originating site for purposes of treatment of a SUD or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a SUD diagnosis. These domiciliary/home visits contain the same elements and similar descriptors to the O/O E/M visits, and therefore, we believe there is sufficient justification to add them to the Medicare telehealth services list on a Category 1 basis. We are adding these to the telehealth services list because an office/outpatient visit might not always most accurately or specifically describe the type of visit furnished to treat an individual in their home for an SUD or co-occuring mental health disorder; and that sometimes one of the domiciliary/home visit codes would more accurately describe the service.

Comment: One commenter stated that Assessment and Care Planning for Patients with Cognitive Impairment (CPT Code 99483) should not be added at this time until more study can be done to assess the appropriateness of this service being delivered in the telehealth context given that many cognitive impairments and symptoms may require in-person assessment.

Response: We continue to believe that CPT code 99483 is sufficiently similar to an office visit to warrant addition to the Medicare telehealth list on a permanent basis in that it involves evaluating and managing a patient's cognitive impairment in an office/outpatient setting. When the AMA CPT Editorial Panel created this code, they assumed that the work associated with assessment and care planning for patients with cognitive impairment had been reported with CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family*), which is currently on the Medicare telehealth list.

After considering the public comments received, we are finalizing our proposal and adding HCPCS codes G2211 and CPT codes 90853, 96121, G2212, 99483, 99334, 99335, 99347, and 99348 to the Medicare telehealth list for CY 2021.

Comment: Commenters expressed opposition to CMS' decision not to propose to add Medical Genetics services (CPT code 96040) to the Medicare telehealth services list.

Response: We note that CPT code 96040 is not separately billable under the PFS; it is considered bundled into O/O E/M visits, which are already on the Medicare telehealth services list. Therefore, we believe it is unnecessary, and could potentially be confusing, to add CPT code 96040 to the list. Only codes that are separately billable can be added to the Medicare telehealth list. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73096 through 73097), physicians and NPPs who furnish and bill Medicare for these services would generally report office or other outpatient E/M CPT codes for office visits that involve significant counseling, including genetic counseling; and the office visit CPT codes are already on the Medicare telehealth services list. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. Genetic counselors are not among the practitioners who can bill Medicare directly for their professional services, and they are also not practitioners who can furnish telehealth services as specified in section 1834(m)(4)(E) of the Act. As such, we do not believe that it would be necessary or appropriate to add CPT code 96040 to the Medicare telehealth services list.

c. Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services From the Medicare Telehealth Services List

Legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020)), to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19. We established several flexibilities to accommodate these

changes in the delivery of care. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for COVID–19.[1] We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. In the March 31st COVID–19 IFC, we added 89 services to the Medicare telehealth services list on an interim basis. Through the ''Medicare and Medicaid Programs; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (IFC), (which was issued on May 1, 2020, and was effective upon publication in the May 8, 2020 **Federal Register** (85 FR 27550 through 27649)) (hereinafter referred to as the ''May 8th COVID–19 IFC''), on an interim basis for the duration of the PHE for COVID–19, we removed the requirement in our regulations that we undertake rulemaking to add or delete services on the Medicare telehealth services list so that we could consider the addition of services on a subregulatory basis as they were recommended by the public or identified internally. On a subregulatory basis, we simultaneously added 46 more services to the Medicare telehealth services list on an interim basis when we issued the May 8th COVID–19 IFC. Finally, on October 14, 2020 we added 11 more services to the Medicare telehealth list on a subregulatory basis. For a full list of Medicare telehealth services please see the CMS website: *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*.

At the conclusion of the PHE for COVID–19, these waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through the regular notice and comment rulemaking process, including the previously established Medicare telehealth services list, as modified by subsequent changes in policies and additions to the telehealth services list adopted through rulemaking, including in this final rule. We believe that the experiences of clinicians who are furnishing telehealth services during the PHE for COVID–19 will be useful to inform decisions about which of the services we added temporarily to the Medicare telehealth services list might be appropriate to add on a permanent basis. However, we also recognize that the annual PFS rulemaking schedule may not align perfectly with the expiration of the PHE for COVID–19, and that the clinicians providing services via telehealth during the PHE may not have the opportunity to conduct the kinds of review or develop the kind of evidence we usually consider when adding services to the Medicare telehealth services list on a permanent basis. In the event that the PHE for COVID–19 ends prior to the end of CY 2021, stakeholders might not have the opportunity to use our current consideration process for telehealth services to request permanent additions to the Medicare telehealth services list prior to those services being removed from the Medicare telehealth services list. This is especially true for those services that might need to be considered on a Category 2 basis, which involves providing supporting documentation to illustrate the clinical benefit of such services. Recognizing the extent to which practice patterns are shifting as a result of the PHE for COVID–19 from a model of care based on in-person services to one that relies on a combination of in-person services and virtual care, we noted that we believe that it would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for these services when furnished via telehealth as soon as the PHE for COVID–19 ends without first providing an opportunity to use information developed during the PHE to support requests for permanent changes to the Medicare telehealth services list.

As previously noted, in response to the PHE for COVID–19, we added a broad range of services to the Medicare telehealth services list. Before eliminating the full range of these services from the Medicare telehealth services list and potentially jeopardizing beneficiary access to those services that have been clinically beneficial, based primarily on the timing of annual rulemaking, we noted that we believe it would be prudent to collect information from the public regarding which, where, and how various telehealth services have been in use in various communities during the COVID–19 response. Feedback from patients and clinicians is essential to helping CMS understand how the use of telehealth services may have contributed positively to, or negatively affected, the quality of care provided to beneficiaries during the PHE for COVID–19, enabling us to better determine which services should be retained on the Medicare telehealth services list until we can give them full consideration under our established rulemaking process.

Therefore, we proposed to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. This new category would describe services that would be included on the Medicare telehealth services list on a temporary basis. We would include in this category the services that were added during the PHE for COVID–19 for which there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. Recognizing that the services we would add on a temporary basis under Category 3 would ultimately need to meet the criteria under categories 1 or 2 in order to be permanently added to the Medicare telehealth services list, and the potential for evidence development that could continue through the Category 3 temporary addition period, we considered each of the services we added on an interim final basis during the PHE for COVID–19.

In developing the proposal to add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth outside the circumstances of the PHE for COVID–19 and that we anticipate would be able to demonstrate that clinical benefit in such a way as to meet our Category 2 criteria in full. Any service added under the proposed Category 3 would remain on the Medicare telehealth services list through the calendar year in which the PHE for COVID–19 ends. When assessing whether there was a potential likelihood of clinical benefit for a service such that it should be added to the Medicare telehealth services list on a Category 3 basis, we considered the following factors:

- Whether, outside of the circumstances of the PHE for COVID–19, there are increased concerns for patient safety if the service is furnished as a telehealth service.
- Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

[1] *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.*

• Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

We recognized that the circumstances of the PHE for COVID–19 have provided clinicians with the opportunity to use telecommunications technology in health care delivery in a scope and manner far surpassing the telehealth services described under section 1834(m) of the Act, particularly as a result of the removal of geographic and site of service restrictions, and the addition of many services to the Medicare telehealth services list. When adding services to the Medicare telehealth services list on an interim basis during the PHE for COVID–19, we reassessed services on a Category 2 basis in the context of the widespread presence of COVID–19 in the community. We recognized that healthcare access issues could arise due to the immediate potential exposure risks to patients and healthcare workers, and that the use of telecommunication technology could mitigate risk and facilitate clinically appropriate treatment. In the context of the PHE for COVID–19. We found that all of the added services met the Category 2 criteria on the basis that there is a patient population who would otherwise not have access to clinically appropriate care (85 FR 19234). While the interim addition of a broad swath of services to the Medicare telehealth services list is responsive to critical needs during the PHE for COVID–19, the impact of adding these services to the Medicare telehealth services list on a permanent basis is currently unknown. Specifically, although it is possible to assess the uptake among health care practitioners of the added telehealth services, the extent to which service delivery via telehealth demonstrates clinical benefit outside the conditions of the PHE for COVID–19 is not known. Adding services to the Medicare telehealth services list on a Category 3 basis will give the public the opportunity to gather data and generate requests to add certain services to the Medicare telehealth services list permanently, which would be adjudicated on a Category 1 or Category 2 basis during future PFS annual rulemaking, while maintaining access to telehealth services with potential likelihood of clinical benefit. We proposed that the Category 3 criteria and the basis for considering additions to the Medicare telehealth services list would be temporary, to expire at the end of the calendar year in which the PHE for COVID–19 expires.

We identified a number of services that we believe, based on our clinical assessment, fit the Category 3 criteria enumerated above in that we did not identify significant concerns over patient safety, quality of care, or the ability of clinicians to provide all elements of the service remotely if these services were to remain on the Medicare telehealth services list for an additional period beyond the PHE for COVID–19. Therefore, we proposed to continue including the services listed in Table 13 on the Medicare telehealth services list through the calendar year in which the PHE for COVID–19 ends. We solicited public comment on the services we identified for temporary addition to the Medicare telehealth services list through the Category 3 criteria, including whether some should not be considered as Category 3 temporary additions to the Medicare telehealth services list, or whether services currently not proposed as Category 3 additions to the Medicare telehealth services list should be considered as such. We noted that while our clinical assessment indicated that the services in Table 13 demonstrate potential likelihood of clinical benefit when furnished as telehealth services and, as such, the potential to meet the Category 1 or Category 2 criteria for permanent addition to the Medicare telehealth services list with the development of additional evidence, we solicited information from the public that would supplement our clinical assessment and assist us in consideration of our proposals regarding the Category 3 addition of services, even though we recognize that formal analyses may not yet be available. The following are examples of the types of information we sought from the public to help inform our decisions about proposed additions under Category 3:

• By whom and for whom are the services being delivered via telehealth during the PHE;

• What practical safeguards are being employed to maintain safety and clinical effectiveness of services delivered via telehealth; and how are practices quickly and efficiently transitioning patients from telehealth to in-person care as needed;

• What specific health outcomes data are being or are capable of being gathered to demonstrate clinical benefit;

• How is technology being used to facilitate the acquisition of clinical information that would otherwise be obtained by a hands-on physical examination if the service was furnished in person. Certain services on the Medicare telehealth services list prior to the PHE, specifically the O/O E/M code set, involve a physical exam. With the telehealth expansions during the PHE, clinicians may have had valuable experience providing other telehealth services to patients in higher acuity settings of care, such as an emergency department, that involve a hands-on physical examination when furnished in person.

• Whether patient outcomes are improved by the addition of one or more services to the Medicare telehealth services list, including whether inclusion on the Medicare telehealth services list increases access, safety, patient satisfaction, and overall quality of care;

• Whether furnishing this service or services via telecommunication technology promotes prudent use of resources;

• Whether the permanent addition of specific, individual services or categories of services to the Medicare telehealth services list supports quick responses to the spread of infectious disease or other emergent circumstances that may require widespread use of telehealth; and

• What is the impact on the health care workforce of the inclusion of one or more services or categories of services on the Medicare telehealth services list (for example, whether the health care workforce and its capabilities to provide care are expanded).

In addition, we noted that CMS is committed to the following broad goals, and these weigh heavily in our decision-making around the addition, whether temporary or permanent, of a service or services to the Medicare telehealth services list. We requested that commenters consider these goals in conjunction with their comments on the proposals for the treatment of the telehealth services we added on an interim basis during the PHE for COVID–19:

• Maintaining the capacity to enable rapid assessment of patterns of care, safety, and outcomes in the Medicare, Medicaid, CHIP, and Marketplace populations;

• Establishing system safeguards to detect and avert unintended patient harms that result from policy adjustments;

• Ensuring high quality care is maintained;

• Demonstrating ongoing quality improvement efforts by Medicare participating providers, while maintaining access to necessary care;

• Establishing protections for vulnerable beneficiary populations (those with multiple chronic conditions, functional limitations, heart failure,

COPD, diabetes, dementia), and sites of heightened vulnerability (such as nursing homes, rural communities) with high risk of adverse outcomes;

- Ensuring appropriate resource utilization and supporting cost efficiency;
- Supporting emergency preparedness and maintaining capacity to surge for potential coronavirus resurgence or other healthcare issues; and
- Considering timing and pace of policy corrections in light of local and regional variations in systems of care and the impact of the PHE for COVID–19.

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TABLE 13: Services Proposed for Temporary Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
	99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.
Home Visits, Established Patient	99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
	99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.
Emergency Department Visits	99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.
	99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.
	99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.
Nursing facilities discharge day management	99315	Nursing facility discharge day management; 30 minutes or less
	99316	Nursing facility discharge day management; more than 30 minutes

Service Type	HCPCS	Long Descriptor
Psychological and Neuropsychological Testing	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)

TABLE 14: Final Services for Temporary Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
End-Stage Renal Disease Monthly Capitation Payment Services	90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
	90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month
Emergency Department Visits	99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.
	99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care

Service Type	HCPCS	Long Descriptor
		professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.
	99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.
	99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.
	99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
	99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.
Home Visits, Established Patient	99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
	99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.

Service Type	HCPCS	Long Descriptor
Nursing facilities discharge day management	99315	Nursing facility discharge day management; 30 minutes or less
	99316	Nursing facility discharge day management; more than 30 minutes
Psychological and Neuropsychological Testing	96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes
	96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
	96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
	96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
Therapy Services, Physical and Occupational Therapy, All levels	97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures

Service Type	HCPCS	Long Descriptor
		addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
	97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

Service Type	HCPCS	Long Descriptor
	97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
	97750	Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes
	97755	Assistive technology assessment (eg, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
	97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
	97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes
	92521	Evaluation of speech fluency (eg, stuttering, cluttering)
	92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);
	92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)
	92524	Behavioral and qualitative analysis of voice and resonance
	92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
Subsequent Observation and Observation Discharge Day Management	99217	Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234-99236 as appropriate.])
	99224	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; Problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99225	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99226	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication

Service Type	HCPCS	Long Descriptor
		or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.
Initial hospital care and hospital discharge day management	99221	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99222	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99223	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99238	Hospital discharge day management; 30 minutes or less
	99239	Hospital discharge day management; more than 30 minutes
Critical Care Services	99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
	99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)
Inpatient Neonatal and Pediatric Critical Care, Subsequent	99469	Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger
	99472	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age
	99476	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age
Continuing Neonatal Intensive Care Services	99478	Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)
	99479	Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)
	99480	Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501-5000 grams)

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We received public comments on the proposed temporary addition of a category 3 basis for adding to or deleting services from the Medicare telehealth services list. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to use a third, temporary category of criteria for adding services to the Medicare telehealth list on a provisional basis. Commenters agreed that keeping certain services added on an interim basis during the PHE for COVID–19 on the Medicare telehealth list on a temporary basis after the end of the PHE will give the medical community time to gather much needed data on services in this category to support Category 2 requests through the regular process for considering additions to the telehealth services list, while maintaining beneficiary access and allowing practitioners to transition back to models of care focused primarily on in-person, rather than virtual, services. The majority of commenters also supported adding the services CMS proposed to add to the Medicare telehealth list on a Category 3 basis.

Response: We appreciate commenters' support for these proposals.

Comment: Most commenters supported the proposed timeframe for services added on a Category 3 basis to remain on the Medicare telehealth list; however, a few commenters stated that adding services to the Medicare telehealth list on a temporary basis would create unnecessary burden for clinicians who are attempting to both treat patients in the midst of a pandemic and develop an evidence base to

support adding these services to the Medicare telehealth list permanently. In addition, by stipulating that certain codes would remain on the list through the year in which the PHE ends, commenters suggested that CMS was creating ambiguity as to when services added to the list on a Category 3 basis would expire. The commenters stated that this would be an impediment to investing in the infrastructure necessary to furnish these services. Some commenters requested that CMS fund the studies necessary to demonstrate whether a given service should be added permanently to the Medicare telehealth list, or at least articulate clear standards CMS would use to assess efficacy.

Response: While we understand commenters' concerns that adding services temporarily to the Medicare telehealth list without a fixed end date would create ambiguity that could serve as a disincentive to providing the services as telehealth services, we would note that the PHE for COVID–19 has now been extended into CY 2021.[2] The extension of the PHE into CY 2021 ensures that clinicians will have at least the entirety of 2021 to collect evidence to support a request to add these services permanently to the Medicare telehealth list.

Comment: Some commenters also expressed concern with the timeframe for which services added on a Category 3 basis will be on the Medicare telehealth list after the conclusion of the PHE. Some commenters suggested alternative timeframes, ranging between 90 days and 2 years after the end of the PHE. Some commenters suggested that CMS should specify a year in which the category 3 additions to the telehealth list will expire, such as 2022.

Response: As stated above, the PHE for COVID–19 has been extended into CY 2021, allowing for services added to the Medicare telehealth list on a Category 3 basis to remain there for at least the entirety of 2021. Any potential extension of this timeframe would be proposed in future rulemaking.

After considering the public comments, we are finalizing the additions in Table 14 to the telehealth list on a Category 3 basis through the later of the end of the year in which the PHE ends or December 31, 2021, as proposed.

[2] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.*

d. Comment Solicitation on Medicare Telehealth Services Added on an Interim Basis During the PHE for COVID–19 That CMS Did Not Propose To Retain After the PHE Ends

In the March 31st COVID–19 IFC and the May 8th COVID–19 IFC, we finalized on an interim basis during the PHE for COVID–19 the addition of a number of services to the Medicare telehealth services list. While a number of these services were previously requested by external stakeholders and reviewed for addition as part of our standard process for updating the Medicare telehealth services list, a few were identified through internal review. As discussed above, we conducted a clinical assessment of each of the services added on an interim basis during the PHE for COVID–19 to the Medicare telehealth services list to identify those for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth outside the circumstances of the PHE for COVID–19. In our clinical review of these services, we did not identify sufficient information to suggest there is a potential likelihood of clinical benefit for the services described below such that they could meet the Category 1 or Category 2 criteria outside the circumstances of the PHE for COVID–19. We specifically considered the potential for these services to be furnished, outside the circumstances of the PHE for COVID–19, without increased concerns for patient safety or jeopardizing quality of care; and furnished fully and effectively, including all elements of the service, by a remotely located clinician via two-way, audio/video telecommunications technology. After assessing these factors, we did not find a potential likelihood that the services could meet Category 2 criteria even with development of additional evidence. As such, we proposed not to extend them on the Medicare telehealth services list beyond the end of the PHE for COVID–19. However, we solicited public comment on whether any service added to the Medicare telehealth services list on an interim basis for the duration of the PHE for COVID–19 should be added to the Medicare telehealth services list on a temporary, Category 3 basis, based on the criteria outlined above. We welcomed additional information from commenters about these services.

We also sought comment on the following considerations associated with particular services. We noted that comments on these specific concerns would inform our final decisions on whether these services should be added to the Medicare telehealth services list on a temporary, Category 3 basis:

- *Initial and final/discharge interactions (CPT codes 99234–99236 and 99238–99239):* We noted that we believe that the potential acuity of the patient described by these codes would require an in-person physical exam in order to fulfill the requirements of the service. We expressed concerns that, without an in-person physical examination, the need for the physician or health care provider to fully understand the health status of the person with whom they are establishing a clinical relationship would be compromised. We noted that we believe the need for an in-person interaction would rise beyond any specific diagnosis, and serves as the foundation upon which any and all clinical decisions are based for these services. We noted that, without an in-person interaction, care planning that includes risk-benefit considerations and clinical decision-making will be less well-informed and create risk of patient harm.
- *Higher level emergency department visits (CPT codes 99284–99285):* We expressed concern that the full scope of service elements of these codes cannot be met via two-way, audio/video telecommunications technology as higher levels are indicated by patient characteristics, clinical complexity, urgency for care, and require complex decision-making. We also noted that we believe, due to the acuity of the patient described by these codes, that an in-person physical examination is necessary to fulfill the service requirements.
- *Hospital, Intensive Care Unit, Emergency care, Observation stays (CPT codes 99217–99220; 99221–99226; 99484–99485, 99468–99472, 99475–99476, and 99477–99480):* These codes describe visits that are furnished to patients who are ill enough to require hospital evaluation and care. We noted that we believe that the codes describe an evaluation for these potentially high acuity patients that is comprehensive and includes an in-person physical examination. Our view that in-person care is necessary to fulfill the requirements of the code is driven by the need for the physician or health provider to fully understand the health status of the person with whom they are establishing a clinical and therapeutic relationship. We also noted that we believe that the need for an in-person interaction would rise above any specific diagnosis, and serves as the foundation upon which any and all clinical decisions are based for these services. We noted that, without an in-

person interaction, care planning that includes risk-benefit considerations and clinical decision-making would be less well-informed and create risk of patient harm. With regard to the physical therapy, occupational therapy, and speech-language pathology services in Table 13, we have received a number of requests that we add therapy services to the Medicare telehealth services list. In the CY 2017 PFS final rule, we noted that section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists (SLPs) are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We stated in the CY 2017 PFS final rule (81 FR 80198) that because these services are predominantly furnished by PTs, OTs, and SLPs, we did not believe it would be appropriate to add them to the Medicare telehealth services list at that time. In a subsequent request to consider adding these services for 2018, the original requester suggested that we might propose these services to be added to the Medicare telehealth services list so that payment can be made for them when furnished via telehealth by physicians or practitioners who can serve as distant site practitioners. We stated that since the majority of the codes are furnished over 90 percent of the time by therapy professionals who are not included on the statutory list of eligible distant site practitioners, we believed that adding therapy services to the Medicare telehealth services list could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth.

In the proposed rule, we noted that we continue to believe this is generally the case, and we did not propose to add these services permanently to the Medicare telehealth services list. We solicited comment on whether these services should be added to the Medicare telehealth services list so that, in instances when a practitioner who is eligible to bill for telehealth services furnishes these services via telehealth, they could bill and receive payment for them. We also solicited comment on whether all aspects of these services can be fully and effectively furnished via two-way, audio/video telecommunications technology. We noted that given our clarification regarding telehealth services furnished incident to the professional services of a physician or practitioner (85 FR 27562), if these services were added to the Medicare telehealth services list, they could be furnished by a therapist and billed by a physician or practitioner who can furnish and bill for telehealth services provided that all of the ''incident to'' requirements are met.

Comment: Commenters expressed concern that we did not propose to add the vast majority of the interim PHE telehealth services to the telehealth list on a Category 3 basis. Commenters stated that, by limiting the availability of these interim PHE telehealth services to the duration of the PHE, CMS would jeopardize access to care for beneficiaries who have come to rely on the provision of these services virtually, and would disrupt practice patterns for those clinicians who were accustomed to furnishing a broader array of telehealth services than included in the proposed permanent and temporary Category 3 additions to the Medicare telehealth list.

Response: We appreciate commenters' concerns. In response, we are finalizing the addition of a broader array of services to the Medicare telehealth list on a Category 3 basis, as described below.

Comment: Many commenters requested that CMS add specific interim PHE telehealth services that we did not propose to the Medicare telehealth list on a Category 3 basis. Most commenters did not provide sufficient (or in some cases, any) evidence to support their requests to be considered under Category 3 criteria. Other commenters did provide additional evidence sufficient to consider certain services on a Category 3 basis. Table 15 includes the complete list of services commenters requested for addition to the CMS Medicare telehealth list on a Category 3 basis.

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TABLE 15: All Category 3 Requests

Code	Long Descriptor
77427	Radiation treatment management, 5 treatments
90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month
92521	Evaluation of speech fluency (e.g., stuttering, cluttering)
92522	Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria);
92523	Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (e.g., receptive and expressive language)
92524	Behavioral and qualitative analysis of voice and resonance
92526	Treatment of swallowing dysfunction and/or oral function for feeding
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording.
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes

Code	Long Descriptor
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An

Code	Long Descriptor
	examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes

Code	Long Descriptor
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
99217	Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234-99236 as appropriate.])
99224	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; Problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.
99225	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.
99226	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.
99234	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.
99235	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
99236	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high

Code	Long Descriptor
	complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit.
99238	Hospital discharge day management; 30 minutes or less
99239	Hospital discharge day management; more than 30 minutes
99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.
99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.
99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.
99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.
99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)
99324	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent with the patient and/or family or caregiver.
99325	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or

Code	Long Descriptor
	family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient and/or family or caregiver.
99326	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent with the patient and/or family or caregiver.
99327	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.
99328	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.
99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.
99341	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.
99342	Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.
99343	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of

Code	Long Descriptor
	moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.
99344	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.
99345	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.
99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.
99468	Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)
99469	Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger
99472	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99476	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age
99478	Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)
99479	Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)
99480	Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501-5000 grams)
G0422	Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session
G0423	Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day

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The following is a summary of these comments and our responses.

Comment: Some commenters requested that we consider adding

initial nursing facility visits, which are currently interim PHE telehealth services, to the telehealth list on a Category 3 basis. Commenters did provide information regarding how telehealth is used in long-term care facilities; however, they did not provide information indicating how the full scope of service elements of an initial nursing facility visit could be furnished via two-way, audio/telecommunications technology.

Response: We continue to believe that there are components of the initial visit, such as the physical exam, that in the vast majority of circumstances can only be properly performed in person given the vulnerability and frailty of this particular patient population. Commenters did not provide evidence to indicate otherwise. We note that patients in a nursing facility may still receive subsequent visits as telehealth services; however, we are not persuaded that these services, in general, could be furnished via telehealth as described by the CPT codes based upon information provided by commenters.

Comment: Many commenters requested that we add physical therapy, occupational therapy, and speech language pathology services to the Medicare telehealth list on a category 3 basis. Commenters provided extensive information on how they furnish these services via two-way, audio/video telecommunications technology. In response to CMS's longstanding concerns that the practitioners who furnish and bill for the overwhelming majority of these services are, outside of the circumstances of the PHE for COVID–19, not among the statutorily authorized practitioners who may independently bill Medicare for telehealth services, commenters pointed to our proposed clarification that telehealth services could be furnished by a therapist incident to the professional services of a billing clinician in accordance with our regulations at § 410.26.

Response: We appreciate the additional information commenters provided suggesting a possible scenario whereby services furnished by therapists may be provided and billed incident to the professional services of a physician or practitioner who is authorized to furnish and bill for telehealth services. While we continue to have concerns as to whether certain elements of therapy services, particularly when provided to new patients, could be furnished in total via two-way, audio/video telecommunications technology, we recognize that the clarification of billing requirements for these services may allow for additional information to be collected and submitted for consideration by CMS. We are therefore finalizing addition of these services to the Medicare telehealth list on a Category 3 basis.

Comment: Some commenters requested that we add several audiology services to the Medicare telehealth list on a Category 3 basis. These codes are currently interim PHE telehealth services. Commenters explained that including CPT codes for device evaluation and therapeutic services with a device is necessary to support access for patients in needs of these assistive technologies, and that not including them would inhibit the ability of speech language pathologists to perform the evaluation and therapeutic services via telehealth.

Response: We note that, outside of the circumstances of the PHE, speech language pathologists are not eligible to independently bill for Medicare telehealth services, although these services could possibly be furnished by a therapist incident to an eligible billing practitioner. Furthermore, we do not agree that the information provided by commenters demonstrates that, under most circumstances, these services can be furnished, in full, via two-way audio/video communication technology given that these codes describe a new patient interaction which would likely require hands-on, clinical assessment and direct, one-on-one interaction/observation.

Comment: Some commenters requested that we add ESRD MCP services with 1 monthly visit to the Medicare telehealth list on a Category 3 basis. Commenters cited information that they say demonstrates that retaining the ESRD-specific telehealth flexibilities post-pandemic would be valuable to both patients and health care providers and would pose no material detriments to patient safety or quality of care. Commenters further offered that technology exists that would enable physicians and other practitioners to deliver effective ESRD care on a virtual basis beyond the PHE for COVID–19. Additionally, commenters noted that it may take time for medically complex and vulnerable patients to travel for in-person care, and that determining when a patient should return to a physician's office should be left to the patient and the physician.

Response: We did not propose to add these services to the Medicare telehealth list on a Category 3 basis due to concerns regarding the patient receiving an adequate physical examination of the vascular access site and in-person evaluation of the patient's fluid status when a patient is only receiving 1 visit per month. We appreciate the additional information provided by commenters, particularly the information on how ESRD services are furnished using audio/video technology outside of the circumstances of the PHE for COVID–19. Based upon this information, we are finalizing the addition of the ESRD MCP services with a single face-to-face visit per month to the Medicare telehealth list on a Category 3 basis. We would note that, during the PHE for the COVID–19 pandemic, section 3705 of the CARES Act allowed for a waiver of the statutory provision in section 1881(b)(3)(B)(ii) of the Act, which requires that an individual determined to have ESRD receiving home dialysis must receive certain face-to-face clinical assessments without the use of telehealth. Therefore, outside of the PHE for COVID–19, for beneficiaries receiving home dialysis services, a face-to-face ESRD-related clinical assessment must be provided in person (without the use of telehealth) for the first 3 months of home dialysis, and once every 3 months thereafter.

Comment: Some commenters requested that we add hospital observation and discharge day management services to the Medicare telehealth list on a Category 3 basis. Commenters cited information that they believe demonstrates that telehealth services in the emergency setting have proven to be successful and add clinical benefit to patients, and that they should be added on a Category 3 basis, if not permanently. Commenters stated that furnishing these services as telehealth services can be helpful or even essential to enable patients to receive high-quality specialty care in isolated rural communities, communities affected by natural disasters, communities affected by local disease outbreaks, and similar situations. Commenters also requested that we add critical care services and established patient neonatal critical care services to the Medicare telehealth list on a Category 3 basis, stating that there are certain situations where it is appropriate to provide higher level and critical care to patients via telehealth. Commenters further offered that the clinical value of telehealth is particularly clear for patients being treated in rural EDs or at rural hospitals where effective telehealth collaboration for high-level cases could facilitate clinical collaboration and decrease unnecessary transfers. Commenters stated that there is a shortage of rural board-certified emergency physicians, and that, if shortages of these physicians continue, more critical care services

may need to be delivered via telehealth over time to ensure that patients receive timely and necessary care. Finally, we received requests to add level four and five emergency department visits to the Medicare telehealth list on a Category 3 basis.

All of these requests were accompanied by robust supporting evidence including information on teleICU and tele-stroke models of care. Commenters also submitted clinical studies pointing to the efficacy of telehealth in more acute care settings.

Response: We are responding to the comments on these codes together because they are all E/M services that are furnished in a hospital or ED setting. We did not propose to add these services to the Medicare telehealth list on a Category 3 basis due to the presumption that in-person assessment and care, particularly an in-person physical exam, was necessary for patients at this level of acuity. Based upon a review of the information provided by commenters, which included information on how distant site practitioners could collaborate with individuals at the originating site (which, outside of the circumstances of the PHE, must be a medical facility) to obtain an accurate and comprehensive evaluation of the patient, we agree that telehealth in the acute settings described by these codes could offer an excellent opportunity for care to patients if both the distant site and originating site facilities/teams have the appropriate infrastructure, technology, and training to effectively conduct such visits via telehealth. We continue to believe that in most instances, in order to fulfill the full scope of service elements described by codes for new patients, an in-person physical exam is necessary; however, we agree that, for services provided to established patients, such as established patient observation services and established patient neonatal critical care, and for emergency department visits and critical care services (the latter of which is being used extensively during the PHE to support surge capacity), more data are needed to understand how these E/M code families are being used in the field and whether their addition to the telehealth services list ultimately could be supported on a Category 2 basis. Therefore, we are finalizing the addition of established patient observation services and established patient neonatal critical care services to the Medicare telehealth list on a Category 3 basis. We are also finalizing the addition of critical care services to the Medicare telehealth list on a Category 3 basis.

Comment: Some commenters requested that we add electronic device management and treatment services to the Medicare telehealth list on a Category 3 basis, stating that safeguards are being developed to deliver safe and effective remote management of neuromodulation technologies during the PHE and beyond. The commenter suggested rationale for monitoring the provision of these services through use of these codes to ensure improved outcomes.

Response: While we appreciate the additional information as to the safeguards being developed to ensure safe access to these services and the information on improved outcomes, it was not clear whether the capability for clinicians to remotely connect to a patient's hand-held device for the purposes of electronic assessment and analysis is widely available. It is also not within CMS's mandate under the PFS to ensure improved outcomes. Therefore, we remain unconvinced by the evidence provided by the commenter that these services can, in most instances, be conducted in full using two-way, audio/video communication technology. We were also uncertain as to which of these services involve a direct, clinical interaction between the patient and practitioner such that, if the service is furnished as a telehealth service, the interaction would be facilitated by audio/video technology; and those that do not involve such an interaction. To the extent these services do not involve a direct, clinical interaction between the patient and practitioner facilitated by audio/video technology, the services would not be subject to the statutory requirements for telehealth services under section 1834(m) of the Act, and there would be no need to consider adding them to the telehealth services list.

Comment: Most commenters supported CMS not adding CPT code 77427 (*Radiation treatment management, 5 treatments*) to the Medicare telehealth list on a Category 3 basis. These commenters stated that, given that most radiation oncology practices have been able to secure adequate PPE, it was no longer necessary for radiation treatment management to be available as a telehealth service. A few commenters disagreed, but did not provide supporting information.

Response: We did not propose to add this service to the Medicare telehealth list on a Category 3 basis due to concerns over whether the full service elements described by CPT code 77427 could, in most cases, be furnished in full via two way, audio-video communication technology. We continue to believe this is the case and appreciate the additional information provided by commenters as to the necessity of adding this service to the Medicare telehealth list on a Category 3 basis.

After considering the public comments, we are finalizing the addition of services to the Medicare telehealth list on a Category 3 basis as explained above and detailed in Table 16.

2. Analysis and Response to the Comment Solicitation on Coding and Payment for Tele-ICU

With regard to the critical care services listed in A–D 5 we have received a number of requests in prior years to add these services to the Medicare telehealth services list. In response to one such request, we finalized creation of two HCPCS G codes, G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 *(Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*), to describe the work associated with furnishing consultation services via Medicare telehealth to critically ill patients in the CY 2017 PFS final rule (81 FR 80196 through 80197). We stated that CPT guidance makes clear that a variety of other services are bundled into the payment rates for critical care, including gastric intubations and vascular access procedures, among others. While we are adding critical care services to the Medicare telehealth list temporarily, on a Category 3 basis, we also solicited comment on whether current coding (either through the CPT codes describing in-person critical care or the HCPCS G codes describing critical care consults furnished via telehealth) does not reflect additional models of critical care delivery, specifically, models of care delivery that utilize a combination of remote monitoring and clinical staff at the location of the beneficiary to allow, when an onsite practitioner is not available, for a practitioner at a distant site to monitor vital signs and direct in-person care as needed.

We sought comment on the definition, potential coding and valuation for this kind of remote service. Specifically, we sought comment on the following concerns:

- How to distinguish the technical component of the remote monitoring portion of the service from the

diagnosis-related group (DRG) payment already being provided to the hospital.

- How to provide payment only for monitoring and interventions furnished to Medicare beneficiaries when the remote intensivist is monitoring multiple patients, some of which may not be Medicare beneficiaries.
- How this service intersects with both the critical care consult G codes and the in-person critical care services.

Comment: One commenter stated that, generally, there are two models of remote critical care services; the first of which is more of a telehealth consultant. Services performed under this scenario may be accurately reported via existing critical care consult G codes. The other model of care includes physicians providing tele-ICU services, which may be enhanced through the use of robotic technology or other methods to complete a remote clinical assessment of the critically ill patient. Commenters stated current critical care consult G-codes may be used for an episodic evaluation and recommendation to the bedside team or may be used for episodic telemedicine consults and do not reflect current models of care. One commenter noted the tele-ICU is involved both before and after the bedside intensivist or physician arrives and leaves the bedside. Several commenters also stated that current CPT and HCPCS coding does not adequately reflect the additional component of monitoring, surveillance, coaching of bedside nurses, physicians who are not intensivists, and active management in real-time and over extended timeframes by tele-ICU Intensivists. Many commenters encouraged CMS to adopt a coding proposal currently under consideration by the CPT editorial panel and the AMA RUC.

Response: We appreciate the feedback regarding the different tele-ICU models. As noted by commenters, the AMA is currently engaged in evaluating coding and valuation for services similar to those identified by commenters. We will keep these comments in mind and look forward to evaluating any new CPT coding and AMA RUC recommendations as part of our future annual rulemaking process.

After considering the public comments, we will consider all of the feedback on the different tele-ICU models of care as well as potential gaps in coding for possible future rulemaking.

TABLE 16: Summary of CY 2021 Services Added to the Medicare Telehealth Services List

Type of Service	Specific Services and CPT Codes
1. Services we are finalizing for permanent addition as Medicare Telehealth Services	• Group Psychotherapy (CPT 90853) • Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99334-99335) • Home Visits, Established Patient (CPT 99347- 99348) • Cognitive Assessment and Care Planning Services (CPT 99483) • Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS G2211) • Prolonged Services (HCPCS G2212) • Psychological and Neuropsychological Testing (CPT 96121)
2. Services we are finalizing to remain temporarily on the Medicare telehealth list through the end of the year in which the PHE for COVID-19 ends (Category 3 services), to allow for continued development of evidence to demonstrate clinical benefit and facilitate post-PHE care transitions.	• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99336-99337) • Home Visits, Established Patient (CPT 99349-99350) • Emergency Department Visits, Levels 1-5 (CPT 99281-99285)* • Nursing facilities discharge day management (CPT 99315-99316) • Psychological and Neuropsychological Testing (CPT 96130- 96133; CPT 96136- 96139) • Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161- 97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507)* • and Hospital discharge day management (CPT 99238- 99239)* • Inpatient Neonatal and Pediatric Critical Care, Subsequent (CPT 99469, 99472, 99476)* • Continuing Neonatal Intensive Care Services (CPT 99478- 99480)* • Critical Care Services (CPT 99291-99292)* • End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962)* • Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224- 99226)*
3. Services we are not adding to the Medicare telehealth list either permanently or temporarily.	• Initial Nursing Facility Visits, All Levels (Low, Moderate, and High Complexity) (CPT 99304-99306) • Initial hospital care (CPT 99221-99223) • Radiation Treatment Management Services (CPT 77427) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324- 99328) • Home Visits, New Patient, all levels (CPT 99341- 99345) • Inpatient Neonatal and Pediatric Critical Care, Initial (CPT 99468, 99471, 99475, 99477) • Initial Neonatal Intensive Care Services (CPT 99477) • Initial Observation and Observation Discharge Day Management (CPT 99218 – 99220; CPT 99234- 99236) • Medical Nutrition Therapy (CPT G0271)

* Services that were not proposed as Category 3 additions to the Medicare telehealth list but are being finalized as such.

3. Technical Refinement to the Medicare Telehealth Services List To Reflect Current Coding

For CY 2020, the CPT Editorial Panel deleted the six existing Health and Behavior Assessment and Intervention procedure CPT codes and replaced them with nine new CPT codes. The six deleted CPT codes include CPT code 96150 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health oriented questionnaires), each 15 minutes face-to-face with the patient;*

initial assessment), CPT code 96151 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health oriented questionnaires), each 15 minutes face-to-face with the patient; reassessment*), CPT code 96152 (*Health and behavior intervention, each 15 minutes, face-to-face; individual*), CPT code 96153 (*Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)*), CPT code 96154 (*Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)*), and CPT code 96155 (*Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)*). However, we inadvertently neglected to make the corresponding update to reflect these coding changes on the Medicare telehealth services list in CY 2020 PFS rulemaking. Therefore, we proposed to delete CPT codes 96150–96155 from the Medicare telehealth services list and replace them with the following successor codes: CPT code 96156 (*Health behavior assessment, including reassessment (i.e., health-focused clinical interview, behavioral observations, clinical decision making)*); CPT code 96158 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*); CPT code 96159 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*); CPT code 96164 (*Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes*); CPT code 96165 (*Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*); CPT code 96167 (*Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes*); CPT code 96168 (*Health behavior intervention, family (with the patient present), face-to-face each additional 15 minutes (list separately in addition to code for primary service)*); CPT code 96170 (*Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*); and CPT code 96171 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*).

We also proposed to amend our regulations to stipulate that when new codes are issued to replace codes that describe the same clinical services that are currently on the Medicare telehealth services list, we would consider those new codes to be successor codes to those that are on the Medicare telehealth services list, and would update the Medicare telehealth services list accordingly. At § 410.78(f), we proposed to revise the final sentence of the paragraph to read: CMS maintains on the CMS website the Medicare telehealth services list under this section, including the current HCPCS codes that describe the services.

We received public comments on the technical refinement to the Medicare telehealth services list to reflect current coding. The following is a summary of the comments we received and our responses.

Comment: Commenters supported this proposal.

Response: We are finalizing this technical refinement as proposed.

4. Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations

The long term care facility regulations at § 483.30(c) require that residents of SNFs receive an initial visit from a physician, and periodic personal visits subsequently by either a physician or other NPP. In the CY 2010 PFS final rule with comment period (74 FR 61762), we stated that these regulations ensure that at least a minimal degree of personal contact between a physician or a qualified NPP and a resident is maintained, both at the point of admission to the facility and periodically during the course of the resident's stay. In that rule we stated that we believe that these federally-mandated visits should be conducted in-person, and not as Medicare telehealth services. Therefore, we revised § 410.78 to restrict physicians and practitioners from using telehealth to furnish the physician visits required under § 483.30(c).

During the PHE for COVID–19, we waived the requirement in 42 CFR 483.30 for physicians and NPPs to perform in-person required visits for nursing home residents, and allowed visits to be conducted via telehealth (*https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*).

We solicited public comment on whether it would be appropriate to maintain this flexibility on a permanent basis outside of the PHE for COVID–19. We invited public comment on whether the in-person visit requirement is necessary, or whether two-way, audio/video telecommunications technology would be sufficient in instances when, due to continued exposure risk, workforce capacity, or other factors, the clinician determines an in-person visit is not necessary.

We also received requests to revise our frequency limitations for telehealth subsequent inpatient and nursing facility visits. We limit the provision of subsequent inpatient visits via Medicare telehealth to once every 3 days and subsequent nursing facility visits to once every 30 days. We received a request to remove the frequency limitation on the subsequent inpatient services and a separate request to revise the subsequent nursing facility visits to once every 3 days, rather than 30 days.

As we stated in the CY 2019 PFS final rule, we believed the potential acuity of illness of hospital inpatients is greater than that of patients who are likely to receive services that were on the Medicare telehealth services list at that time. We also stated that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth to ensure that hospitalized patients have sufficiently frequent encounters with their admitting practitioner. In addition, we expressed our belief that the majority of these visits should be furnished in person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis. Because of our concerns regarding the potential acuity of illness of hospital inpatients, we finalized the addition of CPT codes 99231–99233 to the Medicare telehealth services list, but limited the provision of these subsequent hospital care services through telehealth to once every 3 days. We noted that we continue to believe that admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Our concerns with, and position on, the provision of subsequent hospital care services via telehealth have not changed (83 FR 59493). Therefore, we did not propose to modify the current policy.

In the CY 2018 PFS final rule, we reiterated that we believed it would be appropriate to permit some subsequent nursing facility (NF) care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, but because of our concerns regarding the potential acuity and complexity of NF inpatients, we limited the provision of subsequent NF care services furnished through telehealth to once every 30 days. We also stated that we continued to have concerns regarding more routine use of telehealth given the potential acuity and complexity of NF inpatients, and therefore, we were not proposing to

remove the frequency limitation for subsequent NF care services (83 FR 59494). We received comments from stakeholders who stated that the once every 30-day frequency limitation for subsequent NF visits furnished via Medicare telehealth limits access to care for Medicare beneficiaries in the NF setting. Stakeholders stated that the use of Medicare telehealth is crucial to maintaining a continuum of care in this setting and that CMS should leave it up to clinicians to decide how frequently a visit may be furnished as a Medicare telehealth service rather than in person depending on the needs of specific patients. We noted that we were persuaded by the comments from these stakeholders, and therefore, we proposed to revise the frequency limitation from one visit every 30 days to one visit every 3 days. We noted that we believe this interval strikes the right balance between requiring in-person visits and allowing flexibility to furnish services via telehealth when clinically appropriate to do so. We solicited comment on whether frequency limitations broadly are burdensome and limit access to necessary care when services are available only through telehealth, and how best to ensure that patients are receiving necessary in-person care.

We received public comments on furnishing telehealth visits in inpatient and nursing facility settings, and critical care consultations. The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that CMS revise the long term care facility regulations at § 483.30(c), which require that residents of NFs receive an initial visit from a physician, and periodic personal visits subsequently by either a physician or other NPP, to allow the initial visit to be conducted via Medicare telehealth.

Response: As we stated in the CY 2010 PFS final rule with comment period (74 FR 61762), we continue to believe that in-person contact between a physician or a qualified NPP and a resident is needed at the point of admission to the facility to ensure the appropriate level of care.

Comment: Many commenters have stated their support for revising the frequency limitation for subsequent nursing facility visits furnished via telehealth from once every 30 days to once every 3 days, while other commenters encouraged CMS to remove frequency limitations entirely. A few commenters stated that CMS should maintain some frequency limitations so as to not to create a disincentive for in-person care.

Response: We thank all the commenters for their feedback. As discussed in the proposed rule, we have received requests to revise the frequency limitations on subsequent nursing facility visits from one every 30 days to one every 3 days to align with the frequency limitations in the inpatient setting; however, after additional consideration of the issue, we noted that patients in the nursing facility setting tend to have a longer lengths of stay compared to the patients in the inpatient setting. As such, we have further considered whether the frequency limitations for subsequent nursing facility visits furnished via telehealth should be the same as for the inpatient setting. Additionally, we acknowledge commenters' concerns about creating a disincentive for in-person care in the absence of any frequency limitations on services furnished through telehealth, and that a broader view of our frequency limitation policies across the different Part A and B care settings could potentially lead to inadequate in-person care in certain scenarios. While we appreciate that, in some cases, a subsequent nursing facility visit furnished via telehealth may allow flexibility for practitioners to appropriately treat patients, there are also situations where an in-person visit may be more appropriate. In seeking to find the right balance between providing greater access to care through more telehealth visits and ensuring adequate in-person care, especially given the longer length of stays for NF patients, we believe that one telehealth visit every 30 days may be too infrequent and once every 3 days poses a risk of creating a disincentive for in-person care. Therefore, we believe it is appropriate to revise the frequency limitation for subsequent nursing facility visits to permit one Medicare telehealth visit every 14 days. This limitation provides an appropriate balance between increased access to care through telehealth and maintaining appropriate in-person care.

After consideration of the public comments, we are finalizing a policy to allow subsequent nursing visits to be furnished via Medicare telehealth once every 14 days in the NF setting. We are not finalizing any revisions to the frequency limitations on inpatient visits or critical care consultations provided as telehealth services.

5. Proposed Technical Amendment To Remove References to Specific Technology

The final sentence of our regulation at § 410.78(a)(3) prohibits the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services. In the March 31st COVID–19 IFC, we added a new § 410.78(a)(3)(i) (and reserved § 410.78(a)(3)(ii) for later use) to provide for an exception that removes application of that sentence during the PHE for COVID–19. We added the new section on an interim final basis because we believe that the first sentence of § 410.78(a)(3) adequately describes the technology requirements for an interactive telecommunication system that may be used to furnish a Medicare telehealth service. That sentence defines interactive telecommunication system as ''multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication.'' We noted that we were also concerned that the reference to ''telephones'' in the second sentence of the regulation as impermissible technology could cause confusion in instances where otherwise eligible equipment, such as a smart phone, may also be used as a telephone Because these concerns are not situation- or time-limited to the PHE for COVID–19, we proposed to remove the second sentence of the regulation at § 410.78(a)(3) that specified that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. As we proposed to adopt this change on a permanent basis, we also proposed to delete the paragraphs at § 410.78(a)(3)(i) and (ii). We noted that we believe these amendments to our regulations would remove outdated references to specific types of technology and provide a clearer statement of our policy.

We received public comments on proposed technical amendment to remove references to specific technology. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to amend the regulation. One commenter cited our statement in the March 31st COVID–19 IFC that mobile computing technology colloquially referred to as ''phones'' are now ubiquitous, and the wording of the regulatory text could be construed to prevent their use for purposes of conducting a telehealth service. According to another commenter, advances in digital communication technology should not be unnecessarily excluded as communication methods for patients and clinicians to utilize for telehealth services. Commenters agreed that the reference in the current regulation creates confusion about use

of equipment such as a smart phone or even an interactive telehealth platform operating within an electronic health information system. Commenters agreed that the reference to ''telephones'' in the regulation as an impermissible technology in the final sentence of regulation at § 410.78(a)(3) has caused confusion in instances where equipment, such as smartphones, are also used as a telephone. They state that the references in these sections of the CFR are not situation- or time-limited to the PHE for COVID–19 and should be deleted.

Response: We thank commenters for their support and agree with their stated points. .

After consideration of the comments, we are finalizing this proposed technical amendment.

6. Communication Technology-Based Services (CTBS)

In the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not considered Medicare telehealth services. Specifically, we finalized HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*), and HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*). We finalized maintenance of these codes as part of the set of codes that is only reportable by those practitioners that can furnish E/M services. We stated that we believed this was appropriate since the service describes a check-in directly with the billing practitioner to assess whether an office visit is needed. However, we did note that similar check-ins provided by nurses and other clinical staff can be important aspects of coordinated patient care (83 FR 59486).

In the CY 2020 PFS final rule, we finalized separate payment for HCPCS codes G2061 (*Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), G2062 (*Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and G2063 (*Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*). In that rule, we stated that these codes may be billed by NPPs consistent with the definition of their respective benefit category, although we did not provide specific examples (84 FR 62796).

We received a number of questions regarding which benefit categories HCPCS codes G2061 through G2063 fall under. In the March 31st COVID–19 IFC (85 FR 19244–19245) we established on an interim basis for the duration of the PHE for COVID–19 that these services could be billed for example, by licensed clinical social workers and clinical psychologists, as well as PTs, OTs, and SLPs who bill Medicare directly for their services when the service furnished falls within the scope of these practitioner's benefit categories. In the CY 2021 PFS proposed rule (85 FR 50112 and 50113), we proposed to adopt that policy on a permanent basis. We noted that this is not an exhaustive list and we solicited comment on other benefit categories into which these services may fall.

We also proposed to allow billing of other CTBS by certain NPPs, consistent with the scope of these practitioners' benefit categories, through the creation of two additional HCPCS G codes that can be billed by practitioners who cannot independently bill for E/M services:

- G2250 (*Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.*)
- G2251 (*Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*).

We proposed to value the services identically to HCPCS codes G2010 and G2012, respectively. We acknowledged that it has been agency policy, in general, to differentially value similar services that are performed by practitioners who can and cannot, respectively, bill independently for E/M services, with higher values for the service performed by practitioners who can independently bill E/M services. However, given the relatively low values for HCPCS codes G2010 and G2012, we noted that we did not believe that there was a significant differential in resource costs to warrant different values, but solicited comment on whether we should value these services differentially, including potentially increasing the valuation of HCPCS codes G2010 and G2012.

Further, to facilitate billing of the CTBS by rehabilitative therapists, we proposed to designate HCPCS codes G2250, G2251, G2061, G2062, and G2063 as ''sometimes therapy'' services. When billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTB are furnished as therapy services furnished under an OT, PT, or SLP plan of care.

We also noted that we proposed for CY 2021 to replace the eVisit G-codes with corresponding CPT codes, and that this policy would also apply to those codes.

For all of these CTBS, we also clarified that the consent from the patient to receive these services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. While we continue to believe that beneficiary consent is necessary so that the beneficiary is notified of cost sharing when receiving these services, we noted that we did not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services. We retained the requirement that, in instances when the brief CTBS originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable.

We received public comments on the CTBS proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to replace the eVisit G codes (G2061–G2063) with corresponding CPT codes 98970–98972 for qualified nonphysician health care professional online digital E/M service.

Response: We thank commenters for their feedback. After consideration of the comments received, we are finalizing our proposal to replace G2061–G2063 with CPT codes 98970–98972.

Comment: Many commenters were supportive of the proposal to allow NPPs, such as licensed clinical social workers, clinical psychologists, PTs, OTs, and SLPs to bill HCPCS codes G2061 through G2063, consistent with the definition of their respective benefit category.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing our proposal to allow NPPs, such as licensed clinical social workers, clinical psychologists, PTs, OTs, and SLPs to bill HCPCS codes G2061 through G2063, consistent with the definition of their respective benefit category.

Comment: Commenters requested that CMS clarify that HCPCS codes G2061 through G2063 fell within the scope of the audiology diagnostic benefit category or the medical nutrition therapist benefit category.

Response: We disagree with the commenter. HCPCS codes G2061–G2063 describe online assessment and management while the audiology benefit is for diagnostic testing. Therefore, we believe these services fall outside the audiologists' benefit category. The benefit for medical nutrition therapists is limited by statute to a few specific services described by certain HCPCS codes, which do not include G2061–G2063.

Comment: Many commenters were supportive of the proposal to allow billing of HCPCS codes G2250 and G2251 by certain NPPs, consistent with the scope of these practitioners' benefit categories.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing our proposal to allow billing of HCPCS codes G2250 and G2251 by certain NPPs, consistent with the scope of these practitioners' benefit categories.

Comment: Many commenters supported the proposal to identically value HCPCS codes G2250 and G2251 to G2010 and G2012, respectively.

Response: We thank commenters for their support and feedback.

Comment: One commenter disagreed with the proposal to identically value HCPCS codes G2250 and G2251 to G2010 and G2012, respectively. The commenter stated that services furnished by NPPs should not be valued the same as those provided by physicians and encouraged CMS to increase the valuation of G2010 and G2012 while not offering recommended value for G2250 and G2251.

Response: As we stated in the proposed rule, given the relatively low values for HCPCS codes G2010 and G2012, we do not believe that there is a significant differential in resource costs to warrant differential values for codes G2250 and G2251, and codes G2010 and G2012.

After consideration of the comments, we are finalizing our proposal to identically value HCPCS codes G2250 and G2251 to G2010 and G2012, respectively.

Comment: Several commenters urged CMS to consider increasing the value of G2010 and G2012.

Response: We thank commenters for their feedback and will consider this matter and propose any potential changes through future rulemaking.

Comment: Many commenters supported the proposal to designate HCPCS codes G2250, G2251, G2061, G2062, and G2063 as ''sometimes therapy'' services to facilitate billing of these CTBS by therapists. Including when billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTB are furnished as therapy services furnished under an OT, PT, or SLP plan of care.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing our proposal to designate HCPCS codes G2250, G2251, G2061, G2062, and G2063 as ''sometimes therapy'' services to facilitate billing of the CTBS by therapists. Additionally, we note that when billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTB are furnished as therapy services furnished under an OT, PT, or SLP plan of care.

Comment: Many commenters supported and thanked CMS for the clarification that consent from the patient to receive CTBS services can be documented by auxiliary staff under general supervision as well as by the billing practitioner.

Response: We thank commenters for their feedback.

Comment: Several commenters encouraged CMS to permanently allow the use of virtual check-ins and e-visits for new as well as established patients.

Response: In the CY 2019 PFS proposed rule (83 FR 35724), we created HCPCS code G2012 and stated our expectation that these services would be initiated by the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services. Additionally, MedPAC noted particular concern regarding potential increases in volume that are not related to ongoing, informed patient care. CMS remains concerned about these issues outside of the PHE for COVID–19. As such, we did not propose, and do not anticipate proposing, to permanently allow billing for HCPCS codes G2020 and G2012 when furnished to new patients.

Comment: One commenter suggested it may be helpful for CMS to provide data on specialty-specific uptake of CTBS and e-Visits, both before and after the PHE for COVID–19, in order to determine if there are access challenges in specific specialties.

Response: We thank the commenter for their suggestion and will take this into future consideration after the PHE for COVID–19 ends.

7. Continuation of Payment for Audio-Only Visits

a. Background

In the March 31st COVID–19 IFC, we established separate payment for audio-only telephone E/M services (85 FR 19264 through 19266). The telephone E/M services are CPT codes 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*); 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*); and 99443 (*Telephone evaluation and management service by a physician or other qualified health*

care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion). We noted that, although these services were previously considered non-covered under the PFS, in the context of the PHE for COVID–19 and with the goal of reducing exposure risks associated with COVID–19, especially in the case that two-way, audio and video technology is not available to furnish a Medicare telehealth service, we believed there are circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit. For example, an established patient who was experiencing an exacerbation of their condition could have a 25-minute phone conversation with their physician during which the physician determines that an adjustment to the patient's medication would alleviate their symptoms. The use of CPT code 99443 in this situation prevents a similar in-person service as the evaluation of the patient's symptoms and determination to adjust medication could be conducted without patient and the practitioner being in the same location. We stated our belief that these telephone E/M codes, with their established description and valuation, were the best way to recognize the relative resource costs of these kinds of services and make payment for them under the PFS. For these codes, we initially finalized on an interim basis during the PHE for COVID–19, work RVUs as recommended by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC), as discussed in the CY 2008 PFS final rule with comment period (72 FR 66371), of 0.25 for CPT code 99441, 0.50 for CPT code 99442, and 0.75 for CPT code 99443. We also finalized the RUC-recommended direct PE inputs which consist of 3 minutes of post-service Registered Nurse/Licensed Practical Nurse/Medical Technical Assistant clinical labor time for each code.

In the May 8th COVID–19 IFC, we noted that in the time since we established these payment amounts, stakeholders had informed us that use of audio-only services was more prevalent than we had previously considered, especially because many beneficiaries were not utilizing video-enabled communication technology from their homes. In other words, there were many cases where practitioners would under ordinary circumstances utilize telehealth or in-person visits to evaluate and manage patients' medical concerns, but were instead using audio-only interactions to manage more complex care (85 FR 27589 through 27590). While we had previously acknowledged the likelihood that, under the circumstances of the PHE for COVID–19, more time would be spent interacting with the patient via audio-only technology, we stated that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the PHE for COVID–19 was not accurately captured by the valuation of these services we established in the March 31st COVID–19 IFC. This would be particularly true to the extent that these audio-only services are actually serving as a substitute for office/outpatient Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology contrary to the situation we anticipated when establishing payment for them in the March 31st COVID–19 IFC. We stated that, given our understanding that these audio-only services were being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the O/O E/M codes, we established new RVUs for the telephone E/M services based on crosswalks to the most analogous O/O E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the O/O E/M codes. Specifically, we crosswalked CPT codes 99212, 99213, and 99214 to CPT codes 99441, 99442, and 99443, respectively. We therefore finalized, on an interim basis and for the duration of the PHE for COVID–19, the following work RVUs: 0.48 for CPT code 99441; 0.97 for CPT code 99442; and 1.50 for CPT code 99443. We also finalized the direct PE inputs associated with CPT code 99212 for CPT code 99441, the direct PE inputs associated with CPT code 99213 for CPT code 99442, and the direct PE inputs associated with CPT code 99214 for CPT code 99443. We did not finalize increased payment rates for CPT codes 98966–98968 as these codes describe services furnished by practitioners who cannot independently bill for E/M services and so these telephone assessment and management services, by definition, are not being furnished in lieu of an O/O E/M service. We noted that to the extent that these extended phone services are taking place instead of O/O E/M visits (either in-person or via telehealth), the direct crosswalk of RVUs also better maintains overall budget neutrality and relativity under the PFS. We stated that we believed that the resources required to furnish these services during the PHE for COVID–19 are better captured by the RVUs associated with the level 2–4 established patient O/O E/M visits. Additionally, we stated that, given our understanding that these audio-only services were being furnished as substitutes for O/O E/M services, we recognized that they should be considered as telehealth services, and added them to the Medicare telehealth services list for the duration of the PHE for COVID–19. For these audio-only E/M services, we separately issued a waiver under section 1135(b)(8) of the Act, as amended by section 3703 of the CARES Act, of the requirements under section 1834(m) of the Act and our regulation at § 410.78 that Medicare telehealth services must be furnished using video technology.

b. Summary of Comments Received in Response to Comment Solicitation on Continuation of Payment for Audio-Only Visits

In the CY 2021 PFS proposed rule (85 FR 50113–50114), we did not propose to continue to recognize CPT codes 99441, 99442, and 99443 for payment under the PFS after conclusion of the PHE for COVID–19 because, outside of the circumstances of the PHE, we are not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology. However, we recognized that the need for audio-only interaction could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office; and in that circumstance, a longer phone conversation may be needed to determine if an in-person visit is necessary rather than what is described by the virtual check-in. We solicited comment on whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. We sought input from the public on the appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them. We also solicited comment on whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE for COVID–19 or if

it should be PFS payment policy permanently.

We received public comments on the comment solicitation on continuation of payment for audio-only visits. The following is a summary of the comments we received and our responses.

Comment: Commenters broadly supported maintaining the availability of certain audio-only services after the duration of the PHE for COVID–19. Commenters stated that many beneficiaries may not have access to or choose not to use two-way, audio/video communication technology, and therefore, maintaining some form of payment for audio-only services would be crucial for ensuring access to care for this vulnerable population. Some commenters urged CMS to continue payment for audio-only evaluation or assessment and management services beyond the end of the PHE for COVID–19. Other commenters stated that allowing practitioners to furnish certain behavioral health and counseling services via audio-only communication technology has been crucial to ensuring access to these services and that CMS should continue payment for these audio-only services after the conclusion of the PHE for COVID–19. Commenters further suggested, in response to both this proposal and in the context of the proposed revision to the agency's regulation at § 410.78(a)(3), that the statutory text laying out the telehealth services benefit uses the term ''telecommunications system'' but does not include an explicit definition of that term, except to say that in the case of federal telemedicine demonstrations in Alaska or Hawaii, the term ''includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.'' Therefore, the statute leaves it up to the Department of Health and Human Services (HHS) to determine whether a telehealth telecommunications system must include both audio and video capabilities, and HHS is free to make the modification it proposes under this heading. Based on this assessment, commenters stated that CMS has the authority to redefine our longstanding regulatory interpretation of ''interactive telecommunications system'' at § 410.78 to include audio-only services.

While the majority of commenters stated that they preferred CMS continuing to recognize the audio evaluation/assessment and management services outside of the PHE for COVID–19, some commenters did state that, in the absence of continuing to recognize those codes, CMS should provide coding and payment for a longer virtual check-in. With regard to the valuation of a longer virtual check in, commenters provided a few recommendations. One commenter suggested that we value this service the same as CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family*), other commenters suggested a range of times for a new virtual check in, such as 11–22 minutes or 15–20 minutes. Another commenter suggested that CMS could create more than one additional virtual check-in code.

Response: We appreciate these comments. Section 1834(m)(2)(A) of the Act expressly provides payment to the distant site physician or practitioner of an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system. This means that we pay an equal amount for a service furnished using a ''telecommunications system'' as for a service furnished in person (without the use of a telecommunications system). Section 1834(m)(1) of the Act specifies that telehealth services must be furnished via a ''telecommunications system,'' and it includes an exception to allow ''store and forward'' technology to be considered a telecommunications system only for purposes of certain federal demonstrations. CMS has in place a longstanding interpretation of ''telecommunications system'' that includes only technology that enables a visit that is analogous to an in person visit—which aligns closely with our resource-based payment policy under the PFS, given that payment is made for a telehealth service at the same rate as an in-person visit. Our criteria for considering the addition of services to the telehealth services list also rely on an assessment of whether the service furnished via telehealth is analogous to one furnished in person. We continue to believe that our longstanding regulatory definition of ''telecommunications system'' reflects the intent of statute.

As the audio-only assessment and management or E/M visits are by definition replacements for in-person office visits, they would be subject to the statutory restrictions outlined in section 1834(m) of the Act. Outside of the circumstances of the PHE for COVID–19, we continue to believe that our longstanding regulatory interpretation of ''telecommunications system'' precludes the use of audio-only technology for purposes of Medicare telehealth services.

Comment: Some commenters stated that if CMS continues payment for the audio-only E/M visits, these should continue to be paid at rates commensurate to the level 2–4 established patient office visits, consistent with how these services have been paid during the PHE for COVID–19. Other commenters disagreed, stating that outside the circumstances of the PHE for COVID–19, these services should not have the same payment rate as in-person services.

Response: After the end of the PHE, there will be no separate payment for the audio-only E/M visit codes. At the conclusion of the PHE, we will assign a status of ''bundled'' and post the RUC-recommended RVUs for these codes in accordance with our usual practice.

Comment: A few commenters requested that, if CMS continues to recognize the audio-only evaluation/assessment and management services or if CMS creates a longer virtual check-in service, the service should be available to both new and established patients. A few commenters, including MedPAC, suggested that if CMS creates a longer virtual check-in, the policy should be provisional rather than permanent—for example, through the calendar year in which the PHE for COVID–19 ends.

Response: We continue to believe that, outside of the circumstances of the PHE for COVID–19, CTBS services broadly should be billed only for established patients.

c. Interim Final Rule With Comment Period for Coding and Payment of Virtual Check-In Services (HCPCS Code GSADX1)

i. Background

We note that we have historically established coding and payment on an interim final basis for truly new services when it is in the public interest to do so. Outside of the circumstances of the PHE for COVID–19, Medicare does not provide separate payment for a service that would be a substitute for an in-person visit but is furnished using synchronous audio-only technology. However, we recognize that commenters were clear about the continuing need for coding and payment to reflect the

provision of lengthier audio-only services outside of the PHE for COVID–19, if not as substitutes for in-person services, then as a tool to determine whether an in-person visit is needed, particularly as beneficiaries may still be cautious about exposure risks associated with in-person services.

ii. Interim Final Policy

Given the widespread concerns expressed by commenters about the continuing need for audio-only conversations with patients, we believe it would be expedient to establish additional coding and payment for an extended audio-only assessment service on an interim basis for CY 2021. We believe that establishing payment for this service on an interim basis will support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. Therefore, for CY 2021, on an interim basis, we are establishing HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*.). We are finalizing a direct crosswalk to CPT code 99442, the value of which we believe most accurately reflects the resources associated with a longer service delivered via synchronous communication technology, which can include audio-only communication. This is consistent with our approach to valuing the virtual check-in service (HCPCS code G2012), which used CPT code 99441 as the basis for valuation. In the case of HCPCS code G2252 and CPT code 99442, both codes describe 11–20 minutes of medical discussion when the practitioner may not necessarily be able to visualize the patient, and is used when the acuity of the patient's problem is not necessarily likely to warrant a visit, but when the needs of the particular patient require more assessment time from the practitioner. In the case of HCPCS code G2252, the additional time would be used to determine the necessity of an in person visit result in a work time/intensity that is similar to the crosswalk code. We are finalizing a work RVU of 0.50, direct PE inputs of 3 minutes of clinical labor code L037D, and 1 minute, 15 minutes, and 5 minutes of pre, intra and post service time, respectively. As this service is not a substitute for an in-person visit, but rather an assessment to determine the need for one, the restrictions in section 1834(m) of the Act do not apply and the only technological requirement is that the communication technology must be synchronous. If this service originates from a related E/M service provided within the previous 7 days or leads to an E/M service or procedure within the next 24 hours or soonest available appointment it would be considered bundled into that in-person service. We would consider this service to be a CTBS and refer readers to the CY 2019 PFS final rule for additional discussion as to why these fall outside of the restrictions in 1834(m) of the Act (83 FR 59482 through 59491). We also note that HCPCS code GSADX1 is subject to the same billing requirements as HCPCS code G2012.

iii. Waiver of Proposed Rulemaking for Provisions

Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b), an agency is generally required to publish a notice and solicit comment on a proposed rule in the **Federal Register** before issuing a final rule. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. The APA provides for exceptions from the notice and comment requirements *see* 5 U.S.C. 553(b)(B); in cases in which the APA exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of Title 5 and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements if the agency for good cause finds that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to widespread concerns expressed by commenters about the continuing need for audio-only conversations with patients. We believe that establishing payment for this service on an interim basis will support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. We find that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing these payment policies on an interim basis. We also find that delaying implementation of these policies is unnecessary because the impact on other PFS services for 2021 is negligible and the practical alternative for this treatment is no payment under Medicare Part B. In either case, payments for 2022 and beyond would be informed by public comments.

Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 1871(b)(2)(C) of the Act and section 533(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

8. Comment Solicitation on Coding and Payment for Virtual Services

The health care community uses the term ''telehealth'' broadly to refer to medical services furnished via communications technology. Under current PFS payment rules, Medicare routinely pays for many of these kinds of services. This includes some kinds of remote patient monitoring (either as separate services or as parts of bundled services), interpretations of diagnostic tests when furnished remotely and, under conditions specified in section 1834(m) of the Act, services that would otherwise be furnished in person but are instead furnished via real-time, interactive communication technology. Over the past several years, we have also established several PFS policies to make separate payment for non-face-to-face services included as part of ongoing care management. Although all of the kinds of services stated above might be called ''telehealth'' by patients, payers of health care services, and health care providers, we have generally used the term ''Medicare telehealth services'' to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real time telecommunication technology.

In the CY 2021 PFS proposed rule, we noted that we believe that the provisions in section 1834(m) of the Act apply particularly to the kinds of professional services explicitly enumerated in the statutory provisions,

like professional consultations, office visits, and office psychiatry services. Generally, the services we have added to the Medicare telehealth services list are similar to these kinds of services. As has long been the case, certain other kinds of services that are furnished remotely using communications technology are not considered ''Medicare telehealth services'' and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of the provisions in section 1834(m) of the Act and do not usually include patient interaction (such as remote interpretation of diagnostic imaging tests), and for services that were not discretely defined or separately paid for at the time of enactment and that do include patient interaction (such as chronic care management services).

In recent years, we have begun making separate payment for a number of services that use telecommunications technology but are not considered Medicare telehealth services. These CTB services include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), a virtual check-in, and a remote asynchronous service. These services are different than the kinds of services specified in section 1834(m) of the Act, in that they are not the kind of services that are ordinarily furnished in person but are routinely furnished using a telecommunications system.

In the past, we have received requests to add certain services, such as chronic care management or remote physiologic monitoring to the Medicare telehealth services list. However, as these services fall outside the scope of services addressed, and the enumerated list of services included, in section 1834(m) of the Act, they are not considered telehealth services and, therefore, are not subject to the same restrictions. We solicited comment on whether there are additional services that fall outside the scope of telehealth services under section 1834(m) of the Act where it would be helpful for us to clarify that the services are inherently non-face-to-face, so do not need to be on the Medicare telehealth services list in order to be billed and paid when furnished using telecommunications technology rather than in person with the patient present. We also solicited comment on physicians' services that use evolving technologies to improve patient care that may not be fully recognized by current PFS coding and payment, including, for example, additional or more specific coding for care management services. Finally, we solicited comment on any impediments that contribute to healthcare provider burden and that may result in practitioners being reluctant to bill for CTBS. We noted that we appreciate the ongoing engagement and additional information from stakeholders as we work to improve coding and payment for these services that utilize telecommunications technology.

We received public comments on the comment solicitation on coding and payment for virtual services. The following is a summary of the comments we received and our responses.

Comment: Some commenters stated that CMS should provide utilization information for CTBS services before, during, and after the PHE. Others suggested that CMS establish separate coding and payment for additional consultations that may be furnished using communication technology. Other comments suggested that CMS issue clear and consistent guidance on how to code for and appropriately document both telehealth and CTBS. Commenters recommended that CMS collaborate with the AMA to accurately value services furnished using communication technology.

Response: We thank commenters for their input and will consider them for potential future rulemaking or future subregulatory guidance, as appropriate.

9. Clarification of Current PFS Policies for Telehealth Services

In response to the waiver of statutory requirements and the relaxation of regulatory requirements for telehealth during the PHE for COVID–19, we received a number of requests to clarify existing PFS policy for telehealth. For example, we received questions as to whether Medicare allows incident-to billing for telehealth services, particularly for practitioners such as counselors who are supervised by a physician in private practice. We noted that there are no Medicare regulations that explicitly prohibit eligible distant site practitioners from billing for telehealth services provided incident to their services. However, we also noted that our existing definition of direct supervision requires on-site presence of the billing clinician when the service is provided. That requirement could make it difficult for a billing clinician to provide the direct supervision of services provided via telehealth that is required for services furnished incident to their professional services by auxiliary personnel. Under the proposed revision to the definition of direct supervision to permit virtual presence (FR 85 50114 and 50115), we acknowledged that billing practitioners could more easily meet the direct supervision requirements for telehealth services provided incident to their services. Consequently, we noted that we believe services provided incident to the professional services of an eligible distant site physician or practitioner could be reported when they meet direct supervision requirements at both the originating and distant site through the virtual presence of the billing physician or practitioner. Therefore, we proposed to clarify that services that may be billed incident-to may be provided via telehealth incident to a physicians' (or authorized NPP's) service and under the direct supervision of the billing professional. This is consistent with a policy clarification that we made through the May 8th COVID–19 IFC (85 FR 27562).

We also received questions as to whether services should be reported as telehealth services when the individual physician or practitioner furnishing the service is in the same location as the beneficiary; for example, if the physician or practitioner furnishing the service is in the same institutional setting but is utilizing telecommunications technology to furnish the service due to exposure risks. We also clarified, as we did in the May 8th COVID–19 IFC (85 FR 27562), that if audio/video technology is used in furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person, and the service would not be subject to any of the telehealth requirements under section 1834(m) of the Act or § 410.78 of our regulations.

We received public comments on these proposed clarifications of current policies for telehealth services. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to amend the definition of direct supervision to permit supervision through virtual presence because it would allow billing practitioners to more easily meet the direct supervision requirements for telehealth services provided ''incident to'' their services. Commenters stated that this policy would expand access to needed care in communities that may not have a supervising physician on site, and could make available services that another qualified healthcare professional could provide within their scope of practice if only they had the necessary direct supervision.

Response: We appreciate commenters' support for this clarification. We are

finalizing our proposed clarification that telehealth services may be furnished and billed when provided incident to a distant site physicians' (or authorized NPP's) service under the direct supervision of the billing professional provided through virtual presence in accordance with our regulation at § 410.26.

Comment: One commenter requested that we specify in detail how time should be counted for services furnished and billed incident to the commenter's professional services when the required direct supervision is provided through virtual presence.

Response: As we do not provide specific coding guidance, we suggest that this commenter refer to the AMA CPT guidelines for using time to bill for services furnished and also contact their Medicare Administrative Contractor for further assistance. We further note that time should be counted for telehealth services furnished by auxiliary personnel incident to a billing professional's services in the same way time is counted for other ''incident to'' services.

Comment: Commenters supported our clarification that, if audio/video technology is used while furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person. In addition, the service would not be subject to any of the telehealth requirements, such as geographic or site restrictions. Commenters state that this flexibility helps conserve personal protective equipment (PPE) and supports access to care.

Response: We appreciate commenters' support for this clarification.

Comment: One commenter recommended that CMS institute tracking methods to accurately attribute services to the professional who delivered the care when submitting services using Medicare's ''incident to'' billing provision. They reasoned that, when there is a lack of transparency regarding which clinicians are providing what services, it is difficult, if not impossible, to appropriately measure the type or volume of services or the quality of care delivered by each health professional.

Response: We thank commenters for their feedback and suggestions. We note that CMS has very clear rules about when a physician or practitioner is permitted to bill for services furnished incident to their own. When practitioners bill for their services, they attest to the accuracy of the information they provide; and failure to provide accurate information can result in civil and criminal liability.

10. Direct Supervision by Interactive Telecommunications Technology

Many services for which payment is made under the PFS can be furnished under a level of physician or NPP supervision rather than being performed directly by the billing practitioner. In many cases, the supervision requirements necessitate the presence of the physician or NPP in a particular location, usually in the same location as the beneficiary when the service is provided. For example, as described at § 410.26, services furnished by auxiliary personnel incident to a physician's or NPP's professional service usually require the direct supervision of the physician or NPP. In addition to these ''incident to'' services, there are a number of diagnostic services under the PFS that also must be furnished under direct supervision. As currently defined in §§ 410.26 and 410.32(b)(3)(ii), direct supervision means that the physician or NPP must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision does not require the physician or NPP to be present in the room when the service or procedure is performed.

For the duration of the PHE for COVID–19, for purposes of limiting exposure to COVID–19, we adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR 19245). We recognized that in some cases, the physical proximity of the physician or practitioner might present additional infection exposure risk to the patient and/or practitioner. In the context of the PHE for COVID–19, given the risks of exposure, the immediate risk of foregone medical care, the increased demand for healthcare professionals, and the widespread use of telecommunications technology, we believed that individual practitioners were in the best position to make decisions about how to meet the requirement to provide appropriate direct supervision based on their clinical judgment in particular circumstances.

We proposed to extend the policy until the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, to recognize the different and unique circumstances faced by individual communities that may continue after the PHE ends, and provide time to solicit public input on circumstances where the flexibility to use interactive audio/video real-time communications technology to provide virtual direct supervision could still be needed and appropriate. The extension of this flexibility would allow time for clinicians to make adjustments and for us to obtain public input on services and circumstances for which this policy might be appropriate on a permanent basis. We noted that if the proposal were finalized and the PHE for COVID–19 ended before the CY 2021 PFS final rule takes effect, the interim policy adopted during the PHE to allow direct supervision using real-time, interactive audio and video technology would no longer be in effect during the period between expiration of the PHE and the date the final policy takes effect.

Given our continued interaction with practitioners during the PHE for COVID–19 and our growing understanding of how services may be furnished remotely and safely, we noted that we have a better understanding of how, in some cases, depending upon the unique circumstances of individual patients and billing practitioners or physicians, telecommunications technology could safely allow the practitioner or physician's immediate availability to furnish assistance and direction without necessarily requiring the supervising practitioner's or physician's physical presence in the location where the service is being furnished. In such cases, the use of real-time, audio and video telecommunications technology may allow the supervising practitioner or physician to observe the beneficiary and the auxiliary staff performing the service or be engaged (Direct supervision does not require the physician or NPP to be present in the room when the service or procedure is performed) to provide assistance and direction of the service through virtual means, and without the supervising practitioner or physician being physically present.

Consequently, we proposed to revise § 410.32(b)(3)(ii) to allow direct supervision to be provided using real-time, interactive audio and video technology through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. Specifically, we proposed to continue our current rule that ''Direct supervision'' in the office setting would mean the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It would not mean that the physician (or other

supervising practitioner) must be present in the room when the procedure is performed. We proposed to add that, until the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, the presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only) subject to the clinical judgement of the supervising physician or (other supervising practitioner). In response to questions received since we issued the interim policy for the PHE for COVID–19, we clarified that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure.

While flexibility to provide direct supervision through audio/video real-time communications technology was adopted to be responsive to critical needs during the PHE for COVID–19 to ensure beneficiary access to care, reduce exposure risk and to increase the capacity of practitioners and physicians to respond to COVID–19, we expressed concern that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis, beyond the PHE for COVID–19, due to issues of patient safety. For instance, in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change, and we believe it is necessary for such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation. For example, there could be a case in which a practitioner or physician uses audio/video interactive communications to virtually supervise a nurse performing a post-op evaluation following surgery for hip fracture, and the nurse might note that the patient is uncooperative. In this scenario, had a full exam been performed directly by the practitioner or physician, or under the in-person supervision of a practitioner or physician who was physically or immediately available in the clinic to provide the necessary direction, the physician or practitioner would have recognized that the patient exhibited signs of crystal-mediated acute arthritis, and that the patient's lack of cooperation was likely due to hypoactive delirium. Instead, the supervising practitioner or physician may not have been able to identify this clinical issue as a result of being available only via audio/video interactive communications technology. In this case, the presence of the supervising practitioner or physician through audio/video interactive communications technology would have been insufficient. There also may be certain patient populations that require greater clinical attentiveness and skill than the supervising practitioner or physician could provide via audio/video interactive communications technology. For example, patients with cognitive impairment or dementia, or patients with communication disabilities, may require the experience and skill of a physically present supervising practitioner or physician to recognize needs such as the need for specialized testing. It may not be possible for a supervising practitioner or physician to recognize or meet these clinical needs while being present for the service only through audio/video interactive communications technology. Moreover, the virtual connection between the individual performing the service and the supervising practitioner or physician could be disrupted, making it challenging for the supervising practitioner or physician to remain immediately available to provide assistance and direction to the physically present clinical staff or auxiliary personnel to furnish appropriate care to the patient.

We solicited information from commenters as to whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use if we were to finalize a policy to permit direct supervision through audio/video interactive communications technology, with consideration of relevant patient safety, clinical appropriateness criteria or other restrictions, on a temporary basis through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, or consider it beyond the time specified. We solicited information on what risks this policy might introduce to beneficiaries as they receive care from practitioners that would supervise care virtually in this way. Further, we solicited comment on potential concerns around induced utilization and fraud, waste, and abuse and how those concerns might be addressed. We also invited commenters to provide data and information about their implementation experience with direct supervision using virtual presence during the PHE for COVID–19, and are interested in comments on the degree of aging and disability competency training that is required for effective use of audio/video real-time communications technology.

We received public comments on the direct supervision by interactive telecommunications technology. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to revise the definition of direct supervision to allow virtual presence of the supervising physician or practitioner using real-time, interactive audio-video technology until the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, stating that this revision will greatly help reduce barriers to access, and that allowing physicians and auxiliary personnel to provide services from two separate locations will work to support the expansion of telehealth services and protects frontline workers by allowing appropriate social distancing.

Response: We thank the commenters for their support and feedback.

Comment: Many commenters requested that CMS make permanent the current temporary regulatory flexibility allowing physicians to provide direct supervision of clinical staff virtually, using real-time audio/video technology. Others opposed the use of virtual direct supervision following the termination of the PHE due to issues of patient safety, stating it may not be possible for a supervising physician to recognize or meet urgent clinical needs while being present for the service, and potentially other services at the same time, only through audio/video interactive communications technology.

We also received a variety of responses to our stated concerns that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis, beyond the PHE for COVID–19, due to issues of patient safety. Many commenters did not share these concerns, stating that there is no situation whereby clinical staff or auxiliary personnel would conduct complex, high-risk, surgical, interventional, or endoscopic procedures under any circumstance other than in-person. Many other commenters shared our patient-safety concerns, citing increased utilization and spending, and the potential for

fraud and abuse. Many stressed that virtual supervision can be done safely in certain scenarios, but it is not warranted in other scenarios. More specifically, some commenters said remote supervision would not be appropriate for in-person diagnostic or therapeutic procedures since the physician would not be physically available to help the individual being supervised if the need arises. Similarly, commenters suggested that it may not be appropriate when a remote physician is not on-site for an E/M service that requires finesse when performing the physical examination in person. According to some commenters, virtual direct supervision would not be appropriate for data interpretation, such as imaging studies or certain physiologic studies, where the patient is not physically present. A commenter agreed with the agency's assessment that anesthesia services must be furnished or supervised in person to allow for rapid, on-site decision-making in the event of an adverse clinical situation. One commenter recommended that CMS provide clarifying language in the final rule to ensure that the supervising physician is in the United States when using audio-visual technology for purposes of direct supervision.

Commenters offered a range of responses and suggestions in the interest of patient safety and program integrity in response to our request for information as to whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use, if we were to finalize a policy to permit direct supervision through audio/video interactive communications technology on a temporary basis. According to some commenters, we should defer entirely to physician judgment to determine clinical appropriateness. Others offered suggestions including that we should closely monitor the use of virtual direct supervision during the interim period to gain information on potential induced utilization or fraud, waste, and abuse concerns. Some commenters stated that virtual direct supervision should be robustly documented to ensure that patients are safely receiving clinically appropriate care from members of the care team. A commenter stated that program integrity concerns could be addressed through provider enrollment rather than through administrative barriers. Other suggestions included: That CMS develop a list of high risk procedures and complex patient populations for whom this policy may not be appropriate; that CMS limit the number of clinicians with whom a supervising physician may simultaneously engage, as well as the number of incident-to relationships in which a supervising physician may be involved at a given time, via audio/video technology; that testing sites that use interactive technologies rely on documentation and training; that we require that a caregiver be present physically with the patient when the services are furnished virtually; and that CMS identify conditions under which the extension of the virtual direct supervision policy may be revoked if evidence suggests such supervision is inadequate.

Response: We appreciate the information and suggestions we received in response to this request for comment. This information will allow us to consider safety and program integrity issues in the context of virtual supervision, and to what degree and on what basis this flexibility could be continued following the PHE. We will consider this and other information as we determine future policy regarding use of communication technology to satisfy direct supervision requirements as well as the best approach for safeguarding patient safety while promoting use of technology to enhance access.

After consideration of the comments, we are finalizing our proposal to allow direct supervision to be provided using real-time, interactive audio and video technology through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021.

11. Comment Solicitation on PFS Payment for Specimen Collection for COVID–19 Tests

When physicians and other practitioners collect specimens for clinical diagnostic laboratory tests as part of their professional services, Medicare generally makes payment for the services under the PFS, though often that payment is bundled into the payment rate for other services, including office and outpatient visits. Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an O/O E/M visit (CPT codes 99201 through 99205, 99211 through 99215). In visits where a patient has a face-to-face interaction with a billing professional with whom they have an established relationship, these services are generally reported with a level 2 through a level 5 visit (CPT codes 99212 through 99215). In cases where the specimen is collected during a visit where the face-to-face interaction only involves clinical staff of the billing professional with whom the patient has an established relationship, these services are generally reported using CPT code 99211.

In the May 8th COVID–19 IFC (85 FR 27604–27605), we finalized on an interim basis that physicians and NPPs may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, if the billing practitioner does not also furnish a higher level E/M service to the patient on the same day. In the CY 2021 PFS proposed rule, we noted that we considered whether to extend or make permanent the policy to allow physicians and NPPs to use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, and solicited public comments on whether we should continue this policy for a period of time, or permanently, after the PHE for COVID–19 ends.

We received public comments in response to our comment solicitation on PFS payment for specimen collection for COVID–19 tests. We appreciate the information and feedback provided. We will consider this information for potential future rulemaking.

12. Finalization of Interim Final Rule Provisions Related to Requirements of the Substance Use Disorder (SUD) Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

a. Expanding Medicare Telehealth Services for the Treatment of Opioid Use Disorder and Other SUDs

In the CY 2019 PFS interim final rule with comment period (83 FR 59452, 59496, Nov. 23, 2018), we implemented on an interim final basis the amendments made by section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018) (the SUPPORT Act) to section 1834(m) of the Act. First, section 2001(a) of the SUPPORT Act removed the originating site geographic requirements under section 1834(m)(4)(C)(i) of the Act for telehealth services furnished on or after July 1, 2019 for the purpose of treating individuals diagnosed with a SUD or a co-occurring mental health disorder, as determined by the Secretary, at an originating site described in section

1834(m)(4)(C)(ii) of the Act, other than an originating site described in subclause (IX) of section 1834(m)(4)(C)(ii) of the Act. Subclause (IX) of section 1834(m)(4)(C)(ii) of the Act refers to a renal dialysis facility, which is only an allowable originating site for purposes of home dialysis monthly ESRD-related clinical assessments in section 1881(b)(3)(B) of the Act. Section 2001(a) of the SUPPORT Act also added the home of an individual as a permissible originating site for telehealth services for the purpose of treating individuals diagnosed with a SUD or a co-occurring mental health disorder. Section 2001(a) of the SUPPORT Act also amended section 1834(m)(2)(B)(ii) of the Act to require that no originating site facility fee will be paid in instances when the individual's home is the originating site. Section 2001(b) of the SUPPORT Act granted the Secretary specific authority to implement the amendments made by section 2001(a) through an interim final rule, and under that authority, we issued such an interim final rule. In accordance with section 1834(m)(4)(C)(ii)(X) of the Act, as amended by section 2001(a) of the SUPPORT for Patients and Communities Act, we revised § 410.78(b)(3) on an interim final basis, by adding § 410.78(b)(3)(xii), which adds the home of an individual as a permissible originating site for telehealth services furnished on or after July 1, 2019 to individuals with a SUD diagnosis for purposes of treatment of a SUD or a co-occurring mental health disorder. We amended § 414.65(b)(3) on an interim final basis to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid when the originating site for these services is the individual's home. Additionally, we added § 410.78(b)(4)(iv)(C) on an interim final basis to specify that the geographic requirements in section 1834(m)(4)(C)(i) of the Act do not apply for telehealth services furnished on or after July 1, 2019, to individuals with a SUD diagnosis for purposes of treatment of a SUD or a co-occurring mental health disorder at an originating site other than a renal dialysis facility. We noted that section 2001 of the SUPPORT Act did not amend section 1834(m)(4)(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. We also noted that practitioners would be responsible for assessing whether individuals have a SUD diagnosis and whether it would be clinically appropriate to furnish telehealth services for the treatment of the individual's SUD or a co-occurring mental health disorder. By billing codes on the Medicare telehealth list with the telehealth place of service code, practitioners would be indicating that the codes billed were used to furnish telehealth services to individuals with a SUD diagnosis for the purpose of treating the SUD or a co-occurring mental health disorder.

Comment: Several commenters expressed support for the changes authorized by section 2001(a) of the SUPPORT Act, noting that these changes that will benefit beneficiaries and advance the use of telehealth as a critical tool to improving access to care. One commenter noted that the changes will mitigate barriers to treatment for this patient population, decreasing stigma associated with seeking mental health and SUD services caused by presenting at a qualified originating site, allow patients to receive services at home, and open access to telehealth services for patients living in urban areas.

Response: We thank the commenters for their comments.

Comment: A few commenters urged CMS to consider expanding this flexibility to beneficiaries without SUDs, particularly those with mental health disorders without a co-occurring SUD.

Response: The interim final changes we adopted to our regulations under § 410.78 described above were based on amendments to the statute made by section 2001(a) of the SUPPORT Act. These amendments were limited to telehealth services furnished to individuals diagnosed with a SUD for purposes of treatment of the SUD or a co-occurring mental health disorder. We do not have the statutory authority at this time to expand these changes to include treatment of mental health disorders that are not co-occurring with a SUD diagnosis.

Comment: A few commenters urged CMS to ensure that the full scope of both SUD treatment services and applicable services for the treatment of co-occurring mental health disorders are included in the Medicare telehealth list in the future, citing examples such as screening, counseling, consultation, psychiatric services, care planning, initiation and continued management of Medication-Assisted Treatment (MAT), and others.

Response: Thank you for your comment. We note that HCPCS codes G2086, G2087, and G2088 were added to the Medicare Telehealth list beginning in CY 2020 (84 FR 62628). These codes describe bundled payments for office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy, and group therapy and counseling. We note that for CY 2021, we are finalizing a revision to these code descriptions to include the treatment of any substance use disorder rather than just OUD. See discussion in this final rule describing expansion of these codes to be inclusive of all SUDs beginning in CY 2021. Also, as discussed earlier in this final rule, we are finalizing the addition of CPT codes 99347 and 99348 (*Home visit for the evaluation and management of an established patient*) to the Medicare Telehealth list for CY 2021, which could be appropriately billed for treatment of an SUD or co-occurring mental health disorder, as well as CPT code 90853 (*Group psychotherapy*). We welcome recommendations of other codes for addition to the Medicare Telehealth list through our usual process by the February 10th deadline.

Comment: One commenter encouraged CMS to amend section 1834(m)(4)(f) of the Act to include MAT and remote opioid treatment as covered services on the Medicare telehealth list in order to provide the care needed to all patients with SUDs, including Opioid Use Disorder.

Response: We do not have the authority to amend the statute; however, the services associated with the provision of MAT in the office setting, such as E/M visits and psychotherapy, are on the Medicare Telehealth List.

Comment: One commenter cautioned against creating any administrative procedures that would complicate billing for these services when furnished via telehealth, which could create a barrier to implementation and stifle the ability of telehealth to be used effectively to facilitate SUD and co-occurring mental health services, while another commenter stated that CMS should publish clear sub-regulatory guidance on how the current Medicare telehealth services can be billed when treating SUD.

Response: As discussed in the CY 2019 PFS interim final rule with comment period (83 FR 59496), we noted that practitioners are responsible for assessing whether individuals have a SUD diagnosis and whether it would be clinically appropriate to furnish telehealth services for the treatment of the individual's SUD or a co-occurring mental health disorder. By billing codes on the Medicare telehealth list with the telehealth place of service code, practitioners would be indicating that the codes billed were used to furnish telehealth services to individuals with a SUD diagnosis for the purpose of

treating the SUD or a co-occurring mental health disorder.

In summary, after consideration of the comments, we are finalizing the interim revisions to the regulation text at §§ 410.78(b)(3) and 414.65(b)(3) described above.

E. Care Management Services and Remote Physiologic Monitoring Services

1. Background

In recent years, we have updated PFS policies to improve payment for care management and coordination. Working with the CPT Editorial Panel and other clinicians, we have expanded the suite of codes describing these services. New CPT codes were created that describe services that involve direct patient contact (for some services, in-person) or do not involve direct patient contact; represent a single encounter, monthly service, or both; are timed services; address specific conditions; and represent the work of the billing practitioner, auxiliary personnel (specifically, clinical staff), or both (*see* Table 17). In this final rule for CY 2021, we continue our work to improve payment for care management services through code refinements related to remote physiologic monitoring (RPM), transitional care management (TCM), and psychiatric collaborative care model (CoCM) services.

TABLE 17: Summary of Care Management Codes

Service	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision) (HCPCS codes G0181, G0182)	Supervision of home health, hospice, per month
ESRD Monthly Services (CPT codes 90951-70)	ESRD management, with and without face-to-face visits, by age, per month
Transitional Care Management (TCM) (adopted in 2013) (CPT codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019, 2020, 2021) (CPT codes 99487, 99489, 99490, 99491, HCPCS code G2058 to be replaced by CPT code 99439, in CY 2021)	Management of all care for patients with two or more serious chronic conditions, timed, per month
Advance Care Planning (ACP) (adopted in 2016) (CPT codes 99497, 99498)	Counseling/discussing advance directives, face-to-face, timed
Behavioral Health Integration (BHI) (adopted in 2017) (CPT codes 99484, 99492, 99493, 99494, HCPCS code G2214)	Management of behavioral health conditions(s), timed, per month
Cognitive Impairment Assessment and Care Planning (adopted in 2017) (CPT code 99483)	Assessment and care planning of cognitive impairment, face-to-face visit
Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (adopted in 2017) (CPT codes 99358, 99359)	Prolonged non-face-to-face E/M work related to a face-to-face visit (other than office/outpatient visits beginning in 2021), timed
Prolonged Office/Outpatient E/M Visit (adopted for 2021) (HCPCS code G2212)	Prolonged face-to-face and/or non-face to face E/M work related to an office/outpatient E/M visit, timed
Remote Physiologic Monitoring Treatment Management Services (RPM) (adopted in 2020) (CPT codes 99457, 99458)	Development and management of a plan of treatment based upon patient physiologic data
Interprofessional Consultation (adopted in 2019) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452)	Inter-practitioner consultation
Principal Care Management (adopted in 2020) (HCPCS codes G2064, G2065)	Management of a single, high risk disease

2. Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)

RPM involves the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. In recent years, we have finalized payment for seven CPT codes in the RPM code family. Five of the seven codes have been the focus of frequent questions from stakeholders.

In response to proposals in the CY 2019 PFS proposed rule (83 FR 35771) and the CY 2020 PFS proposed rule (84 FR 40555 through 40556), stakeholders requested that we clarify how we interpret aspects of the RPM code descriptors for CPT codes 99453, 99454, 99091, and 99457. Commenters asked us, for example, to identify who can furnish RPM services, what kinds of devices can be used to collect data, how data should be collected, and how ''interactive communication'' is defined. We stated in the CY 2020 PFS final rule (84 FR 62697) that we would provide guidance in the future about the codes. For CY 2021, we are clarifying how we

read CPT code descriptors and instructions associated with CPT codes 99453, 99454, 99091, and 99457 (and the add-on code, CPT code 99458) and their use for remote monitoring of physiologic parameters of a patient's health.

The RPM process begins with two PE only codes, CPT codes 99453 and 99454, finalized in the CY 2019 PFS final rule (83 FR 59574 through 59576). As PE only codes, they are valued to include clinical staff time, supplies, and equipment, including the medical device for the typical case of remote monitoring. CPT code 99453 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*) is valued to reflect clinical staff time that includes instructing a patient and/or caregiver about using one or more medical devices. CPT code 99454 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*) is valued to include the medical device or devices supplied to the patient and the programming of the medical device for repeated monitoring. We reviewed the PE inputs for CPT code 99454 in the proposed rule and clarified that the medical devices that are supplied to the patient and used to collect physiologic data are considered equipment and, as such, are direct PE inputs for the code.

Review of CPT prefatory language (CPT® 2021 Professional Codebook (hereafter, CPT Codebook), pp. 52–53) provides additional information about the two PE-only codes. For example, the CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period in order for CPT codes 99453 and 99454 to be billed. Additionally, these two codes are not to be reported for a patient more than once during a 30-day period. This language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected. We also noted that CPT code 99453 can be billed only once per episode of care where an episode of care is defined as ''beginning when the remote physiologic monitoring service is initiated and ends with attainment of targeted treatment goals'' (CPT Codebook, p. 52).

Other stakeholder inquiries about CPT codes 99453 and 99454 focused upon the kinds of medical devices that can be used to collect a patient's physiologic data. Prefatory language in the CPT Codebook states that ''the device must be a medical device as defined by the FDA.'' CPT simply specifies that the device must meet the FDA's definition of a medical device as described in section 201(h) of the Federal, Food, Drug and Cosmetic Act (FFDCA). As discussed in the CY 2021 PFS proposed rule (85 FR 50118), we found no language in the CPT Codebook indicating that a medical device must be FDA cleared as some stakeholders suggested, although such clearance may be appropriate. We also noted that we did not find information that suggested a medical device must be prescribed by a physician, although this could be possible depending upon the medical device. Beyond acknowledging the CPT specification that the medical device supplied for CPT code 99454 must meet the FDA definition of a medical device, we clarified in the proposed rule that the medical device should digitally (that is, automatically) upload patient physiologic data (that is, data are not patient self-recorded and/or self-reported). We also noted that use of the medical device or devices that digitally collect and transmit a patient's physiologic data must, as usual for most Medicare covered services, be reasonable and necessary for the diagnosis or treatment of the patient's illness or injury or to improve the functioning of a malformed body member. Further, we noted that the device must be used to collect and transmit reliable and valid physiologic data that allow understanding of a patient's health status in order to develop and manage a plan of treatment.

The CPT Codebook lists the RPM codes under the main heading Evaluation and Management (E/M). We clarified in the proposed rule that as E/M codes, CPT codes 99453, 99454, 99091, 99457, and 99458, can be ordered and billed only by physicians or NPPs who are eligible to bill Medicare for E/M services.

Although we initially described RPM services in the CY 2019 PFS final rule (83 FR 59574) as services furnished to patients with chronic conditions, we clarified in the CY 2021 PFS proposed rule (85 FR 50118) that practitioners may furnish these services to remotely collect and analyze physiologic data from patients with acute conditions as well as from patients with chronic conditions.

After the data collection period for CPT codes 99453 and 99454, the physiologic data that are collected and transmitted may be analyzed and interpreted as described by CPT code 99091, a code that includes only professional work (that is, there are no direct PE inputs). We finalized payment for CPT code 99091 (*Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days*) in the CY 2018 PFS final rule (82 FR 53013 through 53014). The valuation for CPT code 99091 includes a total time of 40 minutes of physician or NPP work, broken down as follows: 5 minutes of preservice work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation). We noted that stakeholders have expressed confusion about the specification in the code descriptor for CPT code 99091 that the service is furnished by a ''physician or other qualified health care professional, qualified by education, training, licensure/regulation.'' The phrase ''physician or other qualified health care professional'' is defined by CPT as ''an individual who is qualified by education, training, licensure/regulation (when applicable) and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service. These professionals are distinct from ''clinical staff . . . [which refers to] a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service but does not individually report that professional service.'' [3] Accordingly, when referring to a particular service described by a CPT code for Medicare purposes, a physician or other qualified health care professional is an individual whose scope of practice and Medicare benefit category includes the service, and who is authorized to independently bill Medicare for the service. See our previous discussion of this in the CY 2016 PFS final rule at 80 FR 70957. Medicare also covers and makes payment for certain services performed by auxiliary personnel (which includes

[3] CPT Codebook, p. xiv.

clinical staff) ''incident to'' the professional services of the billing practitioner. Our regulation at § 410.26(a) defines auxiliary personnel and delineates the conditions for payment for ''incident to'' services.

After analyzing and interpreting a patient's remotely collected physiologic data, we noted that the next step in the process of RPM is the development of a treatment plan that is informed by the analysis and interpretation of the patient's data. It is at this point that the physician or NPP develops a treatment plan with the patient and/or caregiver (that is, develops a patient-centered plan of care) and then manages the plan until the targeted goals of the treatment plan are attained, which signals the end of the episode of care. CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes*) and its add-on code, CPT code 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)*) describe the treatment and management services associated with RPM. Medicare stakeholders have requested that we clarify aspects of these two codes. The two most frequently asked questions include ''Who can furnish the services described by CPT codes 99457 and 99458? '' and ''What does it mean to have an 'interactive communication' with a patient? ''

We addressed who can furnish CPT codes 99457 and 99458 in the CY 2020 PFS final rule (84 FR 62697 through 62698) when we designated both codes as care management services. We explained that, like other care management services, services described by CPT codes 99457 and 99458 can be furnished by clinical staff under the general supervision of the physician or NPP. We noted that RPM services are not considered to be diagnostic tests; that is, they cannot be furnished and billed by an Independent Diagnostic Testing Facility on the order of a physician or NPP.

The services described by CPT codes 99457 and 99458 are services that are typically furnished remotely using communications technologies that allow ''interactive communication,'' which we read as real-time interaction, between a patient and the physician, NPP, or clinical staff who provide the services. Stakeholders have requested that we define ''interactive communication'' as used in the code descriptors for CPT codes 99457 and 99458. We explained in the proposed rule that we saw this remote, non-face-to-face exchange as being similar to the exchange that occurs in providing services described by HCPCS code G2012, *Brief Communication Technology-Based Service,* which we finalized in the CY 2019 PFS final rule (83 FR 59483 through 59486). We clarified that ''interactive communication'' for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission. As indicated in the code descriptor for CPT code 99457, we believed during the writing of the proposed rule that the interactive communication should total at least 20 minutes of time with the patient over the course of a calendar month for CPT code 99457 to be reported. Each additional 20 minutes of interactive communication between the patient and the physician/NPP/clinical staff would be reported using CPT code 99458. We developed our definition of time using the CPT Codebook. The CPT Codebook states that unless there are code- or code-range specific instructions, parenthetical instructions, or code descriptors to the contrary, time is considered to be ''face-to-face'' time with the patient or patient's caregiver/medical decision-maker. See the CPT Codebook, page xvii for more information about measuring time. Although the services described by CPT codes 99457 and 99458 are not typically in-person services, we interpreted time in the code descriptor to mean the time the practitioner spent in direct, real-time interactive communication with a patient.

Lastly, we proposed to establish as permanent policy two of the changes we made on an interim basis to the requirements for furnishing RPM services in the March 31st and the May 8th COVID–19 IFCs. (See 85 FR 19264 and 85 FR 27605 through 27606 for the interim modifications and clarifications to RPM services in response to the PHE for COVID–19).

Our goals during the PHE for COVID–19 have been to reduce exposure risks to the virus for practitioners and patients while also increasing access to health care services. We eliminated as many obstacles as possible to allow timely delivery of reasonable and necessary health care. We wanted patients to be able to access services quickly and without barriers. With the goals of reducing exposure and increasing access to services, we finalized that RPM services could be furnished to new patients, as well as established patients on an interim basis for the duration of the PHE for COVID–19. We also finalized several policies on an interim basis for the duration of the PHE for COVID–19. These include: (1) Allowing consent to be obtained at the time services are furnished; (2) allowing consent to be obtained by individuals providing RPM services under contract with the billing physician or practitioner; and (3) allowing RPM codes to be billed for a minimum of 2 days of data collection over a 30-day period, rather than the required 16 days of data collection over a 30-day period as provided in the CPT code descriptors.

For CY 2021, we proposed on a permanent basis to allow consent to be obtained at the time that RPM services are furnished. Because the CPT code descriptors do not specify that clinical staff must perform RPM services, we also proposed to allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

When the PHE for COVID–19 ends, we again will require that RPM services be furnished only to an established patient. We believe that a physician or practitioner who has an established relationship with a patient would likely have had an opportunity to provide a new patient E/M service. During the new patient E/M service, the physician or practitioner would have collected relevant patient history and conducted a physical exam, as appropriate. As a result, the physician or practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RPM services to collect and analyze the patient's physiologic data and to develop a treatment plan. Additionally, and in keeping with the CPT prefatory language for CPT codes 99453 and 99454, when the PHE for COVID–19 ends, we will once again require that 16 days of data be collected within 30 days to meet the requirements to bill CPT codes 99453 and 99454.

In response to the May 19, 2020 E.O. 13924, ''Regulatory Relief To Support Economic Recovery,'' (85 FR 31353 through 31356), we solicited comment from the medical community and other members of the public on whether

current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients. We requested information that would help us to understand whether it would be beneficial to consider establishing coding and payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. We expressed interest in understanding whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful. For example, CPT codes 99453 and 99454 currently require use of a medical device as defined by the FDA in section 201(h) of FFDCA that digitally collects and transmits 16 or more days of data every 30 days in order for the codes to be billed; however, some patients may not require remote monitoring for 16 or more days in a 30-day period. For some patients, continuous short-term monitoring might be more appropriate. For example, a post-surgical patient who is recovering at home might benefit from remote monitoring of his or her body temperature as a means of assessing infection and managing medications or dosage. In some clinical situations, monitoring several times throughout a day, over a period of 10 days, may be reasonable and necessary. Sixteen or more days might be unnecessary. We requested information that would help us to understand whether it would be beneficial to consider establishing coding and payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. Specifically, we were interested in understanding whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful. We welcomed comments including any additional information that the medical community and other members of the public believe might provide further clarification on how RPM services are used in clinical practice, and how they might be coded, billed, and valued under the Medicare PFS.

We received public comments on our clarifications and proposals related to digitally stored data services/remote physiologic monitoring/treatment management services. The following is a summary of comments we received and our responses.

Comment: Overall, commenters expressed appreciation and support for the clarifications proposed by CMS regarding RPM CPT codes 99453, 99454, 99091, and 99457 (and the add-on code, CPT code 99458).

Response: We thank commenters for their support, as well as for suggesting additional ways we might interpret the RPM codes. We hope to continue this dialogue as CPT creates more RPM codes.

Comment: A group of commenters disagreed with our clarification that CPT codes 99453, 99454, 99091, 99457, and 99458 can be ordered and billed only by physicians and NPPs who are eligible to bill Medicare for E/M services. Some commenters suggested that we allow the CPT Editorial Panel and the RUC to establish appropriate coding for other practitioners.

Response: We believe that as E/M codes, CPT codes 99453, 99454, 99091, 99457, and 99458, can be ordered and billed only by physicians or NPPs who are eligible to bill Medicare for E/M services. We agree with commenters that additional coding would be necessary, specifically for practitioners who cannot order and bill E/M services.

Comment: Commenters disagreed with our suggestion that CPT codes 99091 and 99457 can be billed together. Commenters reported that these two codes are incompatible and cannot be reported in the same calendar month or in conjunction with one another.

Response: We continue to believe that, if reasonable and necessary, CPT codes 99091 (*Collection & interpretation physiologic data*) and 99457 (*Remote physiologic monitoring treatment management*), given their descriptions of services in the CPT Codebook, could be reported for the same patient. We believe the two codes, as currently described, provide different types of services. We agree with commenters that the CPT Codebook states on page 53, ''Do not report 99091 in conjunction with 99457.'' However, the next section states, ''Do not report 99091 for time in a calendar month when used to meet the criteria for 99339, 99340, 99374, 99375, 99377, 99378, 99379, 99380, 99457, and 99491.'' We note that these two statements suggest that there may be instances where both codes could be billed for the same patient in the same month as long as the same time was not used to meet the criteria for both CPT codes 99091 and 99457. We remind readers that the valuation for CPT code 99091 includes a total time of 40 minutes of physician or NPP work broken down as follows: 5 minutes of pre-service work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation). We believe that in some instances when complex data are collected, more time devoted exclusively to data analysis and interpretation by a physician or NPP may be necessary such that the criteria could be met to bill for both CPT codes 99091 and 99457 within a 30-day period. The medically necessary services associated with all the medical devices for a single patient can be billed by only one practitioner, only once per patient per 30-day period, and only when at least 16 days of data have been collected.

Comment: Commenters suggested that other devices that do not meet the FDA's definition of medical device, but collect physiologic data, should satisfy the requirements of RPM services.

Response: We disagree with the commenters. The prefatory language and code descriptors developed by the CPT Editorial Panel indicate the device must meet the FDA definition of a medical device as found in section 201(h) of the FFDCA.

Comment: One commenter stated that a coding gap exists between physiologic and non-physiologic remote monitoring and stated that additional coding is required for non-physiologic parameters.

Response: We thank the commenter for this insight. We look forward to engaging with stakeholders on this topic to inform how we might consider a ''coding gap'' that exists for services related to remote monitoring for non-physiologic measures of health.

Comment: Several commenters suggested that CMS should allow RPM services to be furnished to new patients, as well as to established patients. Other commenters supported our decision to require that patients be known to the practitioner (established patients) prior to the start of RPM services.

Response: We continue to believe that a physician or NPP who has an established relationship with a patient would possess the information needed to understand the current medical status and needs of the patient prior to ordering RPM services to collect and analyze the patient's physiologic data and to develop a treatment plan. We note that during the PHE for COVID–19, RPM services may be furnished and billed for both new and established patients. We refer readers to the March 31st COVID–19 IFC (85 FR 19264) where we adopted the policy on an interim basis for the duration of the PHE for COVID–19 that RPM services could be furnished to new patients as well as established patients.

After considering public comments, we are not extending this interim policy beyond the end of the PHE for COVID–19. At the conclusion of the PHE, there will need to be an established patient-practitioner relationship in order to bill Medicare for CPT codes 99453, 99454, 99457, and 99458.

Comment: Some commenters suggested that we permit fewer than the required 16 days of monitoring per month that are required to bill CPT codes 99453 and 99454. One commenter indicated that patients and health care personnel are served best by a maximum data collection requirement of 6 days. Another commenter stated that the 8 days we suggested would be best. Another commenter suggested that at least 16 days of data should be required, and when 16 days of data are not collected within the 30-day period, that a modifier should be reported as a means of communicating that the service duration was reduced with an associated reduction in payment.

Response: While we agree that a full 16 days of monitoring may not always be reasonable and necessary, we requested detailed information about meaningful, clinical situations that require fewer days or shorter durations of remote monitoring. We were interested in understanding under what clinical circumstances fewer days of monitoring would be medically reasonable and necessary and allow a practitioner to establish clinically meaningful care. Although we received general support for a reduction in the number of days of data collection required to bill for CPT codes 99453 and 99454, we did not receive specific clinical examples.

After considering public comments, we are not extending the interim policy to permit billing for CPT codes 99453 and 99454 for fewer than 16 days in a 30-day period beyond the end of the PHE for COVID–19. At the conclusion of the PHE for COVID–19, we will require, in accordance with the code descriptors for CPT codes 99453 and 99454, that 16 days of data each 30 days must be collected and transmitted to meet the requirements to bill CPT codes 99453 and 99454.

Comment: A few commenters requested that Independent Diagnostic Testing Facilities (IDTFs) be allowed to bill for RPM services.

Response: As we noted in the proposed rule, RPM services are not considered to be diagnostic tests; therefore, RPM services cannot be furnished and billed by an IDTF on the order of a physician or NPP.

Comment: Commenters agreed with our clarification that practitioners should be allowed to furnish RPM services to patients with acute conditions, as well as patients with chronic conditions.

Response: We thank commenters for their support of our clarification that practitioners may furnish RPM services to patients with acute conditions, as well as patients with chronic conditions.

In the CY 2021 PFS proposed rule, we proposed to make permanent two policies that we adopted in the March 31st COVID–19 IFC (85 FR 19264). We received comments on our proposed policies. The following is a summary of the comments we received and our responses.

Comment: Commenters wrote in favor of our proposal to allow consent to be obtained at the time the services of CPT codes 99453 and 99454 are furnished.

Response: We thank our stakeholders for their comments and support of this proposal.

Comment: Commenters agreed with our proposal to allow auxiliary personnel to furnish the services of CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

Response: We thank commenters for their support of this proposal.

After considering comments related to these two proposals, we are finalizing both as proposed.

3. Transitional Care Management (TCM)

Payment for TCM CPT codes 99495 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision-making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*) and 99496 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within seven calendar days of discharge*) was finalized in the CY 2013 PFS final rule (77 FR 68979 through 68993). At that time, we identified a list of 57 HCPCS codes (see 77 FR 68990 for the original guidance) that we stated could not be billed concurrently with TCM services because of potential duplication of services.

For CY 2020, recognizing that use of TCM services was low when compared to the number of Medicare beneficiaries with eligible discharges and that increased utilization of medically necessary TCM services could improve patient outcomes, one of our proposals included modifying our prior rule that prohibited the billing of TCM services with many other services that we had viewed as duplicative (77 FR 68990). In the CY 2020 PFS final rule (84 FR 62685 through 62687), we finalized a policy to allow concurrent billing of TCM services, when reasonable and necessary, with 16 actively priced (that is, not bundled or non-covered) codes during the 30-day period covered by TCM services. We stated at the time that we would continue to refine our billing policies for TCM through future notice and comment rulemaking.

In the CY 2021 PFS proposed rule (85 FR 50120), we proposed to remove 14 additional actively priced (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM for CY 2021. We noted that we believe that no overlap exists that would warrant preventing concurrent reporting between TCM and the services of these 14 codes. We also proposed to allow the new Chronic Care Management code HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary. We stated that the minutes counted for TCM services cannot also be counted towards other services. Table 18 lists the 15 codes that we proposed could be billed concurrently with TCM services when reasonable and necessary. We welcomed comment on our proposal to allow these additional services to billed concurrently with the TCM service.

We received public comments on the TCM proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters wrote in support of our proposal to allow HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary. Commenters agreed that time should not be double-counted, and that services should not overlap, but should be separately reportable.

Response: We thank the commenters for their support of our proposal to allow HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary.

Comment: Commenters stated that the services described by the 14 ESRD codes proposed for separate payment do not overlap or duplicate TCM services and should be paid separately when reasonable and necessary.

Response: We appreciate the support of commenters.

Comment: A few commenters disagreed with our proposal to allow the

ESRD codes and the chronic care management code HCPCS code G2058 to be billed concurrently with TCM. These commenters instead urged CMS to allow the RUC process and recommendations determine how these codes should be valued/revalued and reported, rather than having CMS apply a different approach.

Response: We recognize that some commenters would prefer that we follow the AMA RUC recommendations for code valuations and billing policies. We appreciate the work the AMA committees, and in particular the RUC, do to provide recommendations. We will continue to consider those recommendations along with other information when we develop values and payment policies under the PFS. We believe that allowing concurrent billing of TCM services with the proposed ESRD codes and HCPCS code G2058, when reasonable and necessary, can improve patient outcomes.

After considering the public comments, we are finalizing our proposal to remove 14 additional actively priced (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM for CY 2021. We also are finalizing our proposal to allow HCPCS code G2058 (which we are finalizing in this rule as new CPT code 99439, see the codes in section II.H. for further information) to be billed concurrently with TCM when reasonable and necessary.

TABLE 18: 15 Additional Codes That Could Be Billed Concurrently with TCM

Code Family	CPT Code	Descriptor
End Stage Renal Disease Services (for ages less than 2 months through 20+ years)	90951	ESRD related services with 4 or more face-to-face visits per month; for patients <2 years of age
	90954	ESRD related services with 4 or more face-to-face visits per month; for patients 2-11 years
	90955	ESRD related services with 2-3 face-to-face visits per month; for patients 2-11 years
	90956	ESRD related services with 1 face-to-face visit per month; for patients 2-11 years
	90957	ESRD related services with 4 or more face-to-face visits per month; for patients 12-19 years
	90958	ESRD related services with 2-3 face-to-face visits per month; for patients 12-19 years
	90959	ESRD related services with 1 face-to-face visit per month; for patients 12-19 years
	90963	ESRD related services for home dialysis per full month; for patients <2 years of age
	90964	ESRD related services for home dialysis per full month; for patients 2-11 years
	90965	ESRD related services for home dialysis per full month; for patients 12-19 years
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90967	ESRD related services for dialysis less than a full month of service; per day; for patients <2 years of age
	90968	ESRD related services for dialysis less than a full month of service; per day; for patients 2-11 years
	90969	ESRD related services for dialysis less than a full month of service; per day; for patients 12-19 years
Complex Chronic Care Management Services	HCPCS G2058 (Beginning CY 2021, CPT code 99439)	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month

4. Psychiatric Collaborative Care Model (CoCM) Services (HCPCS Code G2214)

In the CY 2017 PFS final rule (81 FR 80230), we established G-codes used to bill for monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99492–99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077).

Stakeholders have requested additional coding to capture shorter increments of time spent, for example, when a patient is seen for services, but is then hospitalized or referred for specialized care, and the number of minutes required to bill for services using the current coding is not met. To accurately account for these resources costs, in the CY 2021 PFS proposed rule (85 FR 50121), we proposed to establish a G-code to describe 30 minutes of behavioral health care manager time. Since this code would describe one half of the time described by the existing code that describes subsequent months

of CoCM services, we proposed to price this code based on one half the work and direct PE inputs for CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements):*

- Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant;
- Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health practitioners;
- Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;
- Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;
- Monitoring of patient outcomes using validated rating scales; and
- Relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.), which is assigned a work RVU of 1.53.

Therefore, as proposed, the work RVU for the new proposed code is 0.77. We proposed that this code could be used for either the initial month or subsequent months. We noted that the existing CPT time rules for the CoCM services would apply. As proposed, the code would be:

- *GCOL1:* Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.

We proposed that the required elements listed for CPT code 99493 would also be required elements for billing HCPCS cod GCOL1. Additionally, we proposed that CPT time rules would apply, consistent with the guidance in the CPT codebook for CPT codes 99492–99494.

In the CY 2017 PFS final rule (81 FR 80235), we finalized that CCM and BHI services could be billed during the same month for the same beneficiary if all the requirements to bill each service are separately met. We also proposed that HCPCS code GCOL1 could be billed during the same month as CCM and TCM services, provided that all requirements to report each service are met and time and effort are not counted more than once. We noted that the patient consent requirement would apply to each service independently.

In the CY 2017 PFS final rule (81 FR 80235), we finalized that the psychiatric CoCM services may be furnished under general supervision because we do not believe it is clinically necessary that the professionals on the team who provide services other than the treating practitioner (namely, the behavioral health care manager and the psychiatric consultant) must have the billing practitioner immediately available to them at all times, as would be required under a higher level of supervision. Therefore, consistent with the other codes in this code family (CPT codes 99492–99494), we proposed to add HCPCS code GCOL1 to the list of designated care management services for which we allow general supervision.

We welcomed comments on the proposal to create this new code, as well as the proposed valuation.

We received public comments on the CoCM services (HCPCS code GCOL1) proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the creation of a new code to describe a shorter duration of time than is captured by the existing codes describing the psychiatric collaborative care model, noting that this will provide greater flexibility, remove barriers, and encourage further adoption of this model of care. One commenter opposed implementing this code without obtaining further evidence that it is warranted, while another commenter encouraged CMS to work with the CPT Editorial Panel to create a CPT code that would be available for billing by all payers. One commenter urged CMS to eliminate the copayment and deductible for CoCM and other care management services.

Response: We note that we do not have the statutory authority to remove application of the copayment or deductible for these services. After considering the public comments, we are finalizing the creation of HCPCS code GCOL1 as proposed. We note that HCPCS GCOL1 was a placeholder code identifier. The final code is HCPCS code G2214 (*Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional*). We welcome the opportunity to work with the CPT Editorial Panel in the event they are interested in adopting this code into the CPT code set.

F. Refinements to Values for Certain Services To Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability During the PHE for COVID–19

1. Background

a. Evaluation and Management (E/M) Visits Overview

Physicians and other practitioners who are paid under the PFS bill for common office visits for E/M visits using a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. These CPT codes are broadly referred to as E/M visit codes and historically have included three key components within their code descriptors: History of present illness (history), physical examination (exam), and medical decision-making (MDM).[4]

Currently, there are five levels of O/O E/M visits. There are five codes representing each level for new patients (CPT codes 99201 through 99205), and five codes representing each level for established patients (CPT codes 99211 through 99215). CPT code 99211 (*Level 1 established patient*) is the only code in the O/O E/M visit code set that describes a visit that may be performed by the billing practitioner or by clinical staff under supervision, and that has no specified history, exam or MDM (see Table 19).

In total, E/M visits billed using these CPT codes comprise approximately 40 percent of allowed charges for PFS services; and O/O E/M visits, in particular, comprise approximately 20 percent of allowed charges for PFS services. Within the E/M visits represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed charges for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests.

[4] 2019 CPT Codebook, Evaluation and Management, pages 6 through 13.

Generally, these practitioners include primary care practitioners and certain other specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology, tend to bill more E/M visits on the same day as they bill minor procedures.

b. Overview of Policies Finalized in CY 2020 for CY 2021

In the CY 2020 PFS final rule (84 FR 62844 through 62860), for the O/O E/M visit code set (CPT codes 99201 through 99215), we finalized a policy to generally adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*) and will be effective January 1, 2021. Under this new CPT coding framework, history and exam will no longer be used to select the level of code for O/O E/M visits. Instead, an O/O E/M visit will include a medically appropriate history and exam, when performed. The clinically outdated system for number of body systems/areas reviewed and examined under history and exam will no longer apply, and the history and exam components will only be performed when, and to the extent, reasonable and necessary, and clinically appropriate.

The changes will include deletion of CPT code 99201 *(Level 1 office/outpatient visit, new patient*), which the CPT Editorial Panel decided to eliminate because CPT codes 99201 and 99202 are both straightforward MDM and currently largely differentiated by history and exam elements. Table 19 provides an overview of how the level 1 and level 2 O/O E/M visits are currently structured, demonstrating this current overlap.

TABLE 19: Overview of Levels 1 and 2 Office/Outpatient E/M Visits, CY 2020

CPT Code	Service Overview
CPT code 99201 (level 1 new patient)	• Problem-focused history and exam • Straightforward medical decision-making • Typically 10 minutes face-to-face, presenting problem(s) usually self-limited or minor
CPT code 99202 (level 2 new patient)	• Expanded problem-focused history and exam • Straightforward medical decision-making • Typically 20 minutes face-to-face, presenting problem(s) usually of low to moderate severity
CPT code 99211 (level 1 established patient)	• Evaluation and management that may not require the presence of a physician or other qualified healthcare professional • Typically 5 minutes are spent performing or supervising these services, presenting problem(s) usually minimal
CPT code 99212 (level 2 established patient)	• Problem-focused history and exam • Straightforward medical decision-making • Typically 10 minutes face-to-face, presenting problem(s) usually self-limited or minor

For levels 2 through 5 O/O E/M visits, selection of the code level to report will be based on either the level of MDM (as redefined in the new AMA/CPT guidance framework, also available on the AMA website at *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*) or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time). We continue to believe these policies will further our ongoing effort to reduce administrative burden, improve payment accuracy, and update the O/O E/M visit code set to better reflect the current practice of medicine.

Regarding prolonged visits, we finalized separate payment for a new prolonged visit add-on CPT code (CPT code 99XXX), and discontinued the use of CPT codes 99358 and 99359 (*prolonged E/M visit without direct patient contact*) to report prolonged time associated with O/O E/M visits. We refer readers to the CY 2020 PFS final rule for a detailed discussion of this policy (84 FR 62849 through 62850). We are not opposed in concept to reporting prolonged office/outpatient visit time on a date other than the visit, but we believe there should be a single prolonged code specific to O/O E/M visits that encompasses all related time.

Also, we finalized separate payment for HCPCS code GPC1X, to provide payment for visit complexity inherent to E/M associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition, or a complex condition.

The AMA RUC resurveyed and revalued the revised O/O E/M visit code set, concurrent with the CPT Editorial Panel redefining the services and associated interpretive guidance, and provided us with its recommendations. In the CY 2020 PFS final rule, we also addressed and responded to the AMA RUC recommendations. We finalized new values for CPT codes 99202 through 99215, and assigned RVUs to the new O/O E/M prolonged visit CPT code 99XXX, as well as the new HCPCS code GPC1X. These valuations were finalized with an effective date of January 1, 2021. In Table 20, we provide a summary of the codes and work RVUs finalized in the CY 2020 PFS final rule for CY 2021.

TABLE 20: Summary of Codes and Work RVUs Finalized in the CY 2020 PFS Final Rule for CY 2021

HCPCS Code	Current Total Time (mins)	Current Work RVU	CY 2021 Total Time (mins)	CY 2021 Work RVU
99201	17	0.48	N/A	N/A
99202	22	0.93	22	0.93
99203	29	1.42	40	1.6
99204	45	2.43	60	2.6
99205	67	3.17	85	3.5
99211	7	0.18	7	0.18
99212	16	0.48	18	0.7
99213	23	0.97	30	1.3
99214	40	1.5	49	1.92
99215	55	2.11	70	2.8
G2212	N/A	N/A	15	0.61
G2211	N/A	N/A	11	0.33

c. Continuing Stakeholder Feedback

Since issuing the CY 2020 PFS final rule, we have continued to engage with the stakeholder community on the issues addressed in this section of our CY 2021 PFS final rule. These include the time values for levels 2–5 O/O E/M visit codes, revaluation of services that are analogous to O/O E/M visits, the definition and utilization assumptions for the add-on code for office/outpatient visit complexity (GPC1X), and the required time to report prolonged O/O E/M visits. In the CY 2021 PFS proposed rule (85 FR 50121 through 50139), we included proposals on these topics based on continued feedback from stakeholders in the form of public comments, written requests, meetings, and other formal and informal discussions. In this section of our final rule, we summarize and respond to the public comments we received in response to our CY 2021 PFS proposals, and discuss our final polices.

2. Revisions for CY 2021

a. Time Values for Levels 2–5 Office/Outpatient E/M Visit Codes

In the CY 2020 PFS proposed rule (84 FR 40675), we sought comment on the times associated with the O/O E/M visits as recommended by the AMA RUC. When surveying these services for purposes of valuation, the AMA RUC requested that survey respondents consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a timeframe of 3 days prior to the visit and 7 days after, respectively. In developing its recommendations to us, the AMA RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time. The approach used by the AMA RUC to develop recommendations sometimes resulted in two conflicting sets of times: The component times as surveyed and the total time as surveyed. In the CY 2020 PFS final rule, we finalized adoption of the RUC-recommended times as explained below, but stated that we would continue to consider whether this issue has implications for the PFS broadly. When we establish pre-, intra-, and post-service times for a service under the PFS, these times always sum to the total time. We believe it would be illogical for component times not to sum to the total, and this idea is reflected in our ratesetting system, which requires component times to sum to the total time. Commenters on the CY 2020 PFS proposed rule (84 FR 62849) stated that we should adopt the times as recommended by the RUC, and did not provide any additional details on the times they believed we should use when the total time is not the sum of the component times. Table 21 illustrates the AMA RUC surveyed times for each service period and the surveyed total time. It also shows the actual total time calculated as the sum of the component times.

TABLE 21: RUC-Recommended Pre-, Intra-, Post-Service Times, RUC-Recommended Total Times for CPT codes 99202-99215 and Actual Total Time

HCPCS	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Actual Total Time	RUC-recommended Total Time
99202	2	15	3	20	22
99203	5	25	5	35	40
99204	10	40	10	60	60
99205	14	59	15	88	85
99211		5	2	7	7
99212	2	11	3	16	18
99213	5	20	5	30	30
99214	7	30	10	47	49
99215	10	45	15	70	70

Given the lack of clarity provided by commenters on the CY 2020 PFS proposed rule about why the sum of minutes in the components would differ from the total minutes, and our view and systems requirement that total time must equal the mathematical total of component times, we proposed beginning in CY 2021 to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215. The following is a summary of the comments we received and our responses.

Comment: Some commenters did not support our proposal to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215. These commenters further stated, if we were to use the sum of the component times instead of the RUC-recommended median total time, that we would not be appropriately capturing the physician time for the office visits, which were based on a robust survey, if we were to use the sum of the component times instead of the RUC recommended median total time.

One commenter suggested that the median survey total time for the office visits should be utilized to retain relativity. The commenter explained that, while total time is usually a sum of the pre-, intra- and immediate post-service time, for purposes of the office visit survey, the pre-service time was described as 3 calendar days prior to the office visit, the intra-service time was described as the calendar day of the office visit and the post-service time was described as within 7 days following the office visit. The commenter stated that the median survey total time will not necessarily equal the sum of the median times for each of the 3 time periods because of different practitioner workflow patterns that result in different proportions of the practitioners' times being spent in different components of the service. However, the total times as recommended by the RUC accurately capture the time associated with furnishing the service, regardless of whether that work was performed on the date of encounter or other dates surrounding the office visit. The commenter also suggested that the median of the component times was mathematically more appropriate than the median of the total times, because the function of a median is to limit the influence of outlier values.

Some commenters supported our proposal, stating that the RUC's survey methodology, which included collection of time before and after the day of the encounter, resulted in an overestimation of time and work, and that the total time in the CMS work time database should reflect the sum of the pre-, intra-, and post-times collected using the RUC survey. This methodology is consistent with the total times for all other codes in the fee schedule.

Response: We continue to believe that it would be illogical for component times not to sum to the total, and we reiterate that our ratesetting programs are constructed in a manner that assumes this. While we recognize the value of robust survey data, for purposes of consistency and relativity, we believe we should use a consistent methodology across the fee schedule. Also it is not clear why the RUC surveyed time before and after the date of service since the new CPT coding guidance instructs practitioners to report this time using CPT codes 99358 and 99359 (although CMS will no longer recognize 99358–99359 for this purpose, for reasons discussed elsewhere in this section). Having considered the public comments received, we are finalizing our proposal to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.

b. Revaluing Services That Are Analogous to Office/Outpatient E/M Visits

In our proposed rule, we recognized that there are services other than the global surgical codes for which the values are closely tied to the values of the O/O E/M visit codes. We proposed to increase the valuations for these services commensurate with the valuation increases we previously finalized for the O/O E/M visit codes for 2021. Our proposals took into account input from the public (especially our 2020 comment solicitation on this topic) and our own internal review. We proposed to increase valuations for the following:

- End-Stage Renal Disease Monthly Capitation Payment (ESRD MCP) services.
- Transitional care management (TCM) services.
- Maternity services.
- Cognitive impairment assessment and care planning.
- Annual wellness visits (AWV) and initial preventive physical exam (IPPE).
- Emergency department (ED) visits.
- Therapy evaluations.
- Certain behavioral healthcare services.

Many of these services were valued via a building block methodology and have O/O E/M visits explicitly built into their definition or valuation. We noted that, unlike the global surgical codes, some of these services always include an O/O E/M visit(s) furnished by the reporting practitioner as part of the service, and therefore, it may be appropriate to adjust their valuations commensurate with any changes made to the values for O/O E/M visits. Some of these services do not actually include an E/M visit, but we valued them using a direct crosswalk to the RVUs assigned to an O/O E/M visit(s), and for this

reason they are closely tied to values for O/O E/M visits. Overall, we believed that the magnitude of the changes to the values of the O/O E/M visit codes and the associated redefinitions of the codes themselves are significant enough to warrant an assessment of the accuracy of the values of services containing, or closely analogous to, O/O E/M visits.

We received public comments in response to the CY 2020 PFS proposed rule in support of revaluing certain services commensurate with the new O/O E/M visit values. There was particular support from commenters for revaluing the ESRD (MCP) services, TCM services, cognitive impairment assessment and care planning services, and the (ED) visits. Based on input provided after publication of the CY 2020 PFS final rule by the American College of Obstetricians and Gynecologists (ACOG), we also proposed to revalue the maternity surgical packages, which, unlike other global surgery services, were valued using a methodology, described in more detail below, that allowed the valuation of the composite parts of the package to sum to the total value. Additionally, unlike the 10- and 90-day global surgical services codes (referred to in this section as 10- and 90-day globals), we had never expressed concerns as to the accuracy of the values of the maternity packages, and these services were not part of the policy we adopted to transition all 10- and 90- day globals to 0-day globals (79 FR 67591), though that policy was overridden by statutory amendments before it took effect. We also proposed to revalue certain physical therapy evaluations and behavioral healthcare services as closely analogous to the office/outpatient E/M visits. We did not propose to revalue certain ophthalmology services that the public brought to our attention.

In general, some commenters to the CY 2021 PFS proposed rule indicated that they believe CMS used inconsistent methodologies to revise the proposed RVUs to reflect the marginal increase in office/outpatient E/M visits; that other code sets should go through the same consensus process whereby CMS, CPT and the AMA RUC all agree that the services need to be redefined to better describe existing practice and then be revalued; and that CMS should increase all of the global surgical codes if any single global code is increased to reflect changes to the office/outpatient E/M visits. Other commenters agreed with our proposals and methodologies, and a few suggested additional services that should be revalued as analogous to office/outpatient E/M visits. In the following section of our final rule, we discuss the public comments we received in greater detail, respond to the comments and discuss our final policies. By way of overview, we note that we did not rely on any single factor in deciding whether to consider a given code(s) as analogous to office/outpatient E/M visits. Different factors apply to different services, and we took into consideration all of the factors relevant for the code(s) in question, considered together.

(1) End-Stage Renal Disease Monthly Capitation Payment Services

In the CY 2004 PFS final rule with comment period (68 FR 63216), we established new Level II HCPCS G codes for ESRD services and established MCP rates for them as specified under section 1881(b)(3)(A)(ii) of the Act. For ESRD center-based patients, payment for the G codes varied based on the age of the beneficiary and the number of face-to-face visits furnished each month (for example, 1 visit, 2–3 visits and 4 or more visits). We believed that many physicians would provide 4 or more visits to center-based ESRD patients, and a small proportion would provide 2 to 3 visits or only one visit per month. Under the MCP methodology, to receive the highest payment, a physician would have to furnish at least 4 ESRD-related visits per month. In contrast, payment for home dialysis MCP services only varied by the age of beneficiary. Although we did not initially specify a frequency of required visits for home dialysis MCP services, we stated that we expect physicians to provide clinically appropriate care to manage the home dialysis patient.

The CPT Editorial Panel created new CPT codes to replace the G codes for monthly ESRD-related services, and we finalized the new codes for use under the PFS in CY 2009 (73 FR 69898). The codes created were CPT codes 90951 through 90962 for monthly ESRD-related services with a specified number of visits; CPT codes 90963 through 90966 for monthly ESRD-related services for home dialysis patients; and CPT codes 90967 through 90970 for home dialysis patients with less than a full month of services. The latter set of codes is billed per encounter and valued to be 1/30 of the value of CPT codes 90965 and 90966.

In response to our comment solicitation in the CY 2020 PFS final rule and interim final rule regarding whether to adjust the values of the ESRD MCP codes to reflect the increased values of the office/outpatient E/M visit codes, we received a number of supportive comments. These commenters stated that the MCP bundled payments for all ESRD-related care for a month were constructed using a building block methodology and a number of office/outpatient E/M visits were component parts of those bundles; and that the specified number of visits in the code descriptor must be furnished in order to bill for the service. Commenters also noted that although the values of office/outpatient E/M visit codes have been increased once since the creation of the MCP G codes and once after adoption of the MCP CPT codes, the valuation of the ESRD MCP codes was never adjusted to account for increases to the office/outpatient E/M visit codes. In Table 22, we provide a summary of the visits included in the valuation of each ESRD MCP service.

TABLE 22: Number and Level of Office/Outpatient E/M Visits Bundled into the ESRD MCP Services

HCPCS	Short Descriptor	Bundled Office/Outpatient visit(s)
90951	Esrd serv 4 visits p mo <2yr	13x 99214
90954	Esrd serv 4 vsts p mo 2-11	Crosswalked to CPT code 99471
90955	Esrd srv 2-3 vsts p mo 2-11	1x 99215
		2x 99214
90956	Esrd srv 1 visit p mo 2-11	1x 99215
90957	Esrd srv 4 vsts p mo 12-19	1x 99215
		3x 99214
		3x 99213
90958	Esrd srv 2-3 vsts p mo 12-19	1x 99215
		2x 99214
90959	Esrd serv 1 vst p mo 12-19	1x 99215
90960	Esrd srv 4 visits p mo 20+	1x 99213
		3x 99214
90961	Esrd srv 2-3 vsts p mo 20+	3x 99214
90962	Esrd serv 1 visit p mo 20+	1x 99214
90963	Esrd home pt serv p mo <2yrs	1x 99215
		2x 99214
90964	Esrd home pt serv p mo 2-11	1x 99215
		1x 99214
90965	Esrd home pt serv p mo 12-19	1x 99215
		1x 99214
90966	Esrd home pt serv p mo 20+	3x 99214
90968	Esrd svc pr day pt 2-11	RVU of 90964/30
90969	Esrd svc pr day pt 12-19	RVU of 90965/30
90970	Esrd svc pr day pt 20+	RVU of 90966/30

In the past, we have not updated the valuation of this code set to reflect updates to the valuation of the office/outpatient E/M visit code set, and we do not have information on the number and level of visits actually furnished in connection with these services. So over time, the values of the ESRD MCP codes may have become out of step with valuation of their constituent visits. We believe there is sufficient reason to revalue these services to take into account the changes in valuation for the office/outpatient E/M visits. These services were initially valued using a building block methodology that summed the value of the individual service from its components, and for some of the codes in this code set, a specified number of visits must be furnished in order to bill for the respective ESRD MCP code because they are included in the code descriptor.

Therefore, we noted that we believe that the ESRD MCP codes should be updated to more accurately account for the associated office/outpatient E/M visits. We proposed to increase the work, physician time, and PE inputs in the form of clinical staff time of the ESRD MCP codes based on the marginal difference between the 2020 and 2021 office/outpatient E/M visit work, physician time, and PE inputs built into each code, as summarized in Tables 23 and 24. By improving payment accuracy for the ESRD MCP codes, we would also be supporting broader efforts at advancing kidney health.[5] We noted that we believe the majority of the visits included in the ESRD MCP bundles are being furnished, but sought comment on whether there are instances where the number and/or level of visits being furnished are not consistent with the number and level of visits built into the valuation of the code. The following is a summary of the comments we received and our responses.

Comment: One commenter noted that CMS inadvertently indicated a proposed work RVU of 8.04 for CPT code 90966 in in Table 19 in the CY 2021 PFS proposed rule (85 FR 50129). The commenter urged CMS to finalize a work RVU of 8.04 for this code to help eliminate structural barriers the commenter believes exist to home dialysis, and relieve the disparity in modality choice, as home dialysis receives a low RVU remuneration compared to in-center hemodialysis. Another commenter stated that the work RVU published in Addendum B of the proposed rule, 5.52, is the more accurate value.

Response: We regret the drafting error, and we reiterate that we did indeed propose a work RVU of 5.52 for CPT code 90966 as reflected in Addendum B. While we appreciate the concerns regarding access to care, we agree with comments stating that the proposed work RVU of 5.52 is the more accurate value.

Comment: Some commenters supported our proposal to increase the value of these services in light of previous changes to the E/M visit values. However, some commenters did not support increases to these code values absent a formal review, stating that it would be inconsistent to consider increasing values for some services and not others that are closely tied to the values of the office/outpatient E/M visit codes and/or codes that have E/M visits explicitly built into their definition or valuation, and that these codes should be subject to the same process for other potentially misvalued services. One

[5] HHS Launches President Trump's 'Advancing American Kidney Health' Initiative: *https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html.*

commenter disapproved of our proposed increasing the rates for these services, and stated that not all of the ESRD-related service CPT codes 90951–90962 were valued with a building block methodology of discrete E/M services. These commenters stated that CPT code 90951 was valued using magnitude estimation with a crosswalk to CPT code 99295, while CPT code 90954 was valued with a crosswalk to CPT code 99293. The commenters noted that both CPT code 99293 and 99295 have since been deleted. The commenters further stated that for the rest of the ESRD codes, the numbers and levels of visits were not determined based on surveys that led to use of the building block methodology; rather, they were negotiated using magnitude estimation in comparison to the two codes, CPT codes 99295 and 99293.

Response: Commenters are incorrect as to the methodology used to value CPT code 90951 in the proposed rule (as summarized in Table 22). We adopted the RUC recommended value for this service, which included the value of 13 instances of CPT code 99214 in the bundle. It was not valued using a crosswalk. However, we continue to believe it is accurate to consider these services as being among those for which values are closely tied to the values of the office/outpatient E/M visit codes. The ESRD MCP codes have numbers of visits explicitly built into their definitions, the majority of which we believe are taking place. Proportionate increases for these two codes will also maintain the relative relationships among the codes in this family.

We agree with commenters that CPT code 90954, this code was initially valued based on a crosswalk to CPT code 99293. When CPT code 99293 was deleted, it was replaced by CPT code 99471. By crosswalking CPT code 90954 to CPT code 99471, the relationship established between the two services is preserved. The public may nominate any code(s) as potentially misvalued through the usual misvalued code process or request resurvey or valuation through the AMA RUC.

We did not receive responses to our request for comments on whether there are instances where the number and level of visits actually furnished by practitioners reporting the ESRD MCP services differs from the number and level assumed in the valuation.For example, as shown in Table 22, the valuations included specified numbers and levels of office/outpatient E/M visits, but because the descriptors do not require the same level and number of visits to be furnished in order to report the services, the office/outpatient E/M visit resources assumed to be included in the ESRD services might not actually be expended. CPT code 90957 (*End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month*) was valued with 1x 99215, 3x 99214, and 3x 99213. However, CPT code 90957 includes four or more visits of unspecified levels. Similar to the global surgical codes, this might suggest that we should not ''transfer'' the increase in valuation of the stand-alone office/outpatient E/M visits into these ESRD bundles. Unlike TCM, the number and level of visit included in the ESRD service valuations does not necessarily match the actual services furnished and billed. We continue to be concerned that the number and level of visits built into the valuation of these codes may not accurately reflect the number and level of visits actually being furnished, such that they may be misvalued. We may consider this issue through future rulemaking, as we have for the global surgical codes. However, we still believe the ESRD MCP codes are different from the global surgical codes in that they are valued using building block and involve largely medical care rather than procedural care. The ESRD monthly services include ongoing medical management of a chronic condition, which makes them more similar to the kind of work typically furnished and billed as office/outpatient E/M visits. Therefore, we continue to believe that the ESRD MCP services' valuation should be increased commensurate with the changes made to the values for office/outpatient E/M visits at this time as was proposed, and we are finalizing as proposed.

2. TCM Services (CPT Codes 99495 and 99496)

The goal of TCM services is to improve the health outcomes of patients recently discharged from inpatient and certain outpatient facility stays. We began making separate payment for TCM services in CY 2013. At that time, CPT code 99495 (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*) was valued to include one, level 4 established patient office/outpatient visit, while CPT code 99496 (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge; medical decision making of high complexity during the service period; face-to-face visit within 7 calendar days of discharge*) was valued to include one, level 5 established patient office/outpatient visit (77 FR 68991). In the CY 2020 PFS final rule (84 FR 62687), we finalized the RUC-recommended work and direct PE inputs for the TCM codes which resulted in small RVU increases for both codes.

Because both TCM codes include a required face-to-face E/M visit (either a level 4 or 5 office/outpatient E/M visit), we proposed to increase the work RVUs associated with the TCM codes directly to the new valuations for the level 4 (CPT code 99214) and level 5 (CPT code 99215) office/outpatient E/M visits for established patients. Please see Tables 23 and 24 for long descriptors, as well as current and final work RVUs, physician time, and clinical staff time, for the TCM codes.

Comment: We received several comments specific to TCM, all in support of our proposal to revalue the TCM codes, although they did not provide specific rationale.

Response: We continue to believe that the values for services that explicitly include a single E/M visit of a given setting and level, and that were valued using a direct crosswalk to that visit, should be increased to reflect the new values for the included E/M visit. At this time, we are finalizing our proposed revised values for the two TCM codes shown in Table 23.

3. Maternity Services

In the CY 2002 PFS final rule with comment period (66 FR 55392–55393), we finalized separate global payment for maternity care services. The maternity packages are unique within the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, including visits and other medical care, delivery services (that may include surgical services), and imaging; and were valued using a building-block methodology as opposed to the magnitude estimation method that is commonly used to value the 10- and 90-day global services. Seventeen CPT codes are used to bill for delivery, antepartum, and postpartum maternity care services, and these codes are all designated with a unique global period indicator ''MMM.''

For CY 2021, the AMA RUC made a recommendation to revalue these services, along with their recommendations to revalue the 10- and 90- day global surgical packages, to account for increases in the values of office/outpatient E/M visits. In the CY 2020 PFS final rule, we decided not to make changes to the valuation of 10- and 90- day global surgical packages to reflect changes made to values for the office/outpatient E/M visit codes while we continue to collect and analyze the data on the number and level of office/outpatient E/M visits that are actually being performed as part of these services.

The 10- and 90-day global surgical packages are commonly valued using a methodology known as magnitude estimation. Magnitude estimation refers to a methodology for valuing work that identifies the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS, without explicitly valuing the components of that work. Since its inception, the AMA RUC has worked under the prevailing assumption that magnitude estimation is the standard for valuation of all physicians' services, including those with global surgical packages. Consequently, the work values associated with expected typical E/M visits within a code's global period are not necessarily added to the physician work value for the code to determine the final work RVU. The postoperative visits in the 10- or 90-day global surgical code periods are often valued with reference to RVUs for separately-billed E/M visits, but the bundled post-operative visit RVUs do not directly contribute a certain number of RVUs to the valuation of the procedures.

In contrast, the MMM codes are unique in both the length of the global period and the methodology under which they were valued. When CMS established values for the maternity packages, we based them on RUC recommendations developed by the relevant specialty societies using the building block methodology. When it is used for a CPT code representing a bundle of services, the building block methodology components are the CPT codes that are considered to make up the bundled code and the inputs associated with those codes. Therefore, when the maternity packages were valued, the work (and other inputs) associated with the office/outpatient E/M visits in each package were explicitly included (along with values associated with imaging and other services in the package).

In addition, unlike the global surgical codes, we have reason to believe the visits included in the maternity codes are actually furnished given the evidence-based standards and professional guidelines for obstetrical care. For example, The *Guidelines for Perinatal Care* state that ''a woman with an uncomplicated first pregnancy is examined every 4 weeks for the first 28 weeks of gestation, every 2 weeks until 36 weeks of gestation, and weekly thereafter.''[6] For this reason, we excluded the maternity codes from our recent global surgery data collection.

Given the valuation methodology and expectations for office/outpatient E/M visits in the maternity package codes, and the revaluation recommendation developed by the AMA RUC, we believe that the maternity packages should be updated to more accurately reflect the values of the office/outpatient E/M visits included in the packages. We believe that, due to the use of the building block valuation methodology rather than magnitude estimation, and the likelihood that the bundled visits are actually being furnished, the valuations recommended to us by the AMA RUC more accurately reflect the resource costs associated with furnishing these services. In the past, the work, physician time, and PE for these services have not been revalued to reflect changes to the office/outpatient E/M visits that are included as part of the package and therefore, the valuation of the MMM surgical packages have become misaligned with the valuation of their constituent office visits.

When revaluing the maternity packages, the AMA RUC used a methodology similar to what we used when revaluing the ESRD MCP codes and TCM by adding in the marginal differences in work, physician time, and PE in the form of clinical staff time between the current and 2021 E/M values. We noted that we believe that this method accurately accounts for the increase in valuation relative to the office/outpatient E/M visits. Therefore, we proposed to increase the work RVUs, physician time, and PE inputs in the form of clinical staff time associated with the maternity packages by accepting the revaluation recommendation from the AMA RUC as detailed in Tables 23 and 24.

We also noted that, in addition to appropriately reflecting changes to values of the office and outpatient E/M visits, increases made to the valuation of the maternity package codes would be consistent with our broader focus on improving maternal health and birth outcomes. The proposed changes would account for additional resources involved with additional work that is needed on the part of practitioners to improve care for this patient population, such as risk identification and ensuring appropriate interventions and referrals.[7]

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal regarding the global maternity codes. However, other commenters requested a fair and relative payment for maternity care codes and for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies, not any subset of them using potentially disparate valuation methodologies. Some commenters stated that it is unfair to apply the RUC-recommended E/M value increases to stand-alone E/M visits, select global codes (for example, monthly end-stage renal disease (ESRD) and bundled maternity care), and select bundled services (for example, monthly psychiatric management), but not to the E/M visits that are included in the global surgical packages, and that this will disrupt the relativity of the MPFS.

Response: We continue to believe that the maternity global surgical packages are distinct from the 10- and 90-day globals for the reasons articulated above. We note that commenters did not provide any information to suggest that the number and level of visits accounted for in the valuation of these codes are not being performed. In addition, unlike the global surgical packages, the maternity packages (and the ESRD monthly services discussed above) are focused on ongoing, comprehensive medical care. This kind of care is similar to the type of care typically furnished and billed as office/outpatient E/M visits and, as such, makes the services analogous. Having considered the public comments we received, we are finalizing our proposal to revalue the maternity bundles as recommended by the AMA RUC.

[6] Kilpatrick SJ, Papile L, and Macones GA, eds. AAP Committee on Fetus and Newborn and ACOG Committee on Obstetric Practice. Guidelines for Perinatal Care. Eighth Edition. 2017. Page 150.

[7] *https://www.hhs.gov/blog/2020/01/29/achieving-better-health-mothers-and-babies.html*; *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/21-Maternal-Health-Forum-Improving-Maternal-Health-for-Our-Communities.pdf*; *https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model*.

4. Assessment and Care Planning for Patients With Cognitive Impairment (CPT Code 99483)

In CY 2017, we established payment for HCPCS code G0505 (*Assessment and care planning for patients with cognitive impairment*) to provide payment for cognitive assessment and care planning for patients with cognitive impairments, believing that the CPT Editorial Panel was developing new coding for that service. In response to the CY 2017 PFS proposed rule, the AMA RUC submitted recommended values for this code, which we adopted in the CY 2017 PFS final rule. In CY 2018, the CPT Editorial Panel created CPT code 99483 for reporting of this service and in CY 2018, CMS adopted CPT code 99483 (deleting HCPCS code G0505) without changing the service valuation. Based upon input from commenters and the AMA RUC, the valuation of this service reflected the complexity involved in assessment and care planning for patients with cognitive impairment by including resource costs that are greater than the highest valued office/outpatient E/M visit (CPT code 99205, new patient level 5 visit) (81 FR 80352). Specifically, the service includes an evaluation of a patient's cognitive functioning and requires collecting pertinent history and current cognitive status all of which require medical decision making of moderate or high complexity.

With the forthcoming increased valuation for CPT code 99205 in CY 2021, we noted that the current work RVU for CPT code 99483 would have a lower work RVU than a new patient level 5 office/outpatient E/M visit. Given the way CPT code 99483 was valued initially, we noted that this valuation would create a rank order anomaly between the two codes. Since CPT code 99483 was valued in relation to a level 5 office/outpatient E/M new patient visit, we believed that an adjustment to the work, physician time, and PE for this service to reflect the marginal difference between the value of the level 5 new patient office/outpatient E/M visit in CY 2020 and CY 2021 would be appropriate to maintain payment accuracy. Therefore, we proposed to adjust the work, time, and PE in the form of clinical staff time for CPT code 99483 as shown in Tables 23 and 24. We used the ratio between the CY 2020 and CY 2021 values for the level 5 new patient office/outpatient visits and applied that ratio to increase the value of CPT code 99483 commensurate with the increase to CPT code 99205.

We received public comments on the Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483). The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposal to increase the valuation of CPT code 99483 in order to maintain the relationship between CPT code 99483 and the level 5 new patient office/outpatient visit, which was an important part of the initial valuation. Commenters stated that accurate payment for this service is essential for maintaining access to care for beneficiaries with cognitive impairment.

However, several commenters disagreed with our proposed revaluation of CPT code 99483. These commenters indicated that our proposed increase to CPT code 99483 would create a rank order anomaly between CPT codes 99205 and 99483. Commenters explained that the work RVU and time for code 99483 were based upon survey data and magnitude estimation. The RUC did not use any code as a crosswalk for valuation of CPT code 99483, and CPT code 99205 is not inherent to this service. Commenters suggested that in order to identify the relative valuation for the services of CPT code 99483, the code should be referred to the RUC for review.

Response: While we appreciate the additional insight into the valuation of these codes, we continue to believe that maintaining the value of CPT code 99483 at its current rate would create a rank order anomaly. This service comprises a stand-alone E/M visit that is always furnished; has most of the same components as CPT code 99205, including identical interpretive guidance for level of medical decision making; and was (and continues to appropriately be) valued in direct relation to CPT code 99205. While the cognitive assessment and care planning code was valued using magnitude estimation, these other factors provide additional support for continuing to reflect its exact relationship with the level 5 new patient office/outpatient visit. Therefore, we believe these services are sufficiently analogous to warrant preserving the same relationship. Members of the public can request that the RUC review certain code sets at any time. After consideration of the public comments, we are finalizing this proposal to revalue CPT code 99483 as proposed.

5. Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness Visits (AWV)

In the CY 2011 PFS final rule with comment period, we finalized separate payment for HCPCS codes G0438 (*Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit*) and G0439 (*Annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit*). These services were valued via a direct crosswalk to the work, time, and direct PE inputs associated with CPT codes 99204 and 99214, respectively. In that same rule, we stated that the HCPCS code G0402 (*Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment*) was also valued based on a direct crosswalk to the work, time, and direct PE inputs for CPT code 99204 (75 FR 73408 through 73411).

Because these codes are valued using direct crosswalks to office/outpatient E/M visits, we believed that to maintain payment accuracy for the IPPE and the AWV, their values should be adjusted to reflect the changes in value for CPT codes 99204 and 99214. Therefore, we proposed to revise the work, physician time, and direct PE inputs for these codes as shown in Tables 23 and 24. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with our proposal to revalue the IPPE and AWV HCPCS codes. These commenters agreed that because these services were valued using direct crosswalks to CPT codes 99204 and 99214, their values should be updated to reflect the increases to those visits finalized for CY 2021.

Response: We thank the commenters for their support.

Comment: Several commenters disagreed with our proposal to revalue the IPPE and AWV HCPCS codes. A commenter indicated that because the AMA RUC has never reviewed these codes, it is unclear that the work associated with the services represents work described by a level 4 office/outpatient E/M visit.

Response: We continue to believe that because the IPPE and AWV were valued using direct crosswalks to CPT codes 99204 and 99214, respectively, changes to the work associated with CPT codes 99204 and 99214 should be applied to the valuation of the IPPE and AWV codes. Regarding the point that these codes have not been reviewed by the RUC, we note that the IPPE and AWV are services that are unique to the Medicare program. These services are reported using Medicare-specific HCPCS G codes that are not applicable for other payers. As such, we do not see a need for these codes to be reviewed by

the RUC. If the RUC did review them, however, we would consider any RUC recommendations through our usual rulemaking process. As discussed above, our decision to consider a given code(s) as analogous to the office/outpatient E/M visits is not based on any single factor, but rather, takes into account various applicable factors. The public may nominate any code(s) as potentially misvalued through the usual misvalued code process, or request that codes reviewed by the AMA RUC.

We received comments primarily in support of our proposal to revalue the IPPE and AWV codes. Our proposed revaluations reflect changes in value to the two office and outpatient E/M codes (that is, CPT codes 99204 and 99214) upon which the IPPE and AWV code values were originally crosswalked. We continue to believe that to maintain payment accuracy, the values for the IPPE and AWV codes should be adjusted accordingly. After considering the comments, we are finalizing as proposed.

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TABLE 23: CY 2020 Work RVUs and CY 2021 Final Work RVUs

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Final CY 2021 Work RVUs
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	32.16	36.58
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.01	18.34
59425	Antepartum care only; 4-6 visits	6.31	7.80
59426	Antepartum care only; 7 or more visits	11.16	14.3
59430	Postpartum care only (separate procedure)	2.47	3.22
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	35.64	40.39
59515	Cesarean delivery only; including postpartum care	21.47	22.13
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	33.87	38.29
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	19.73	20.06
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	36.16	40.91
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	22.00	22.66
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	18.46	23.92
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	15.98	15.98
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	8.79	10.32
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	5.95	6.64
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	12.52	15.46
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	8.34	9.87
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of	5.50	6.19

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Final CY 2021 Work RVUs
	parents; with 1 face-to-face visit by a physician or other qualified health care professional per month		
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	5.18	6.77
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	4.26	5.52
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month	3.15	3.57
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	10.56	12.09
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	9.14	10.25
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	8.69	9.80
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	4.26	5.52
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age	0.30	0.34
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age	0.29	0.33
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older	0.14	0.18
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (eg, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.	3.44	3.80

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Final CY 2021 Work RVUs
99492	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.	1.70	1.88
99493	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.	1.53	2.05
99495	Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge	2.36	2.78
99496	Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge; medical decision making of high complexity during the service period; face-to-face visit within 7 calendar days of discharge	3.10	3.79
G0402	Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment	2.43	2.60
G0438	Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit	2.43	2.60
G0439	Annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit	1.50	1.92

TABLE 24: Comparison of Physician Time, and Clinical Staff Time (Non-facility and Facility) for HCPCS Codes, CY 2020 Values vs. CY 2021 Final Values

HCPCS	Phys. Time (Minutes) – CY 2020	Phys. Time (Minutes) – CY 2021 Final	NF Clinical Staff Time (Minutes) - CY2020	NF Clinical Staff Time (Minutes) – CY 2021 Final	Fac. Clinical Staff Time (Minutes) – CY 2020	Fac. Clinical Staff Time (Minutes) – CY 2021 Final
59400	739.5	753.5	N/A	N/A	551.0	551.0
59410	398.5	327.5	N/A	N/A	42.0	42.0
59425	137.0	180.0	206.0	198.0	-	-
59426	252.0	330.0	386.0	378.0	-	-
59430	63.0	77.0	89.0	87.0	-	-
59510	817.5	818.5	N/A	N/A	587.0	587.0
59515	476.5	392.5	N/A	N/A	78.0	78.0
59610	739.5	753.5	N/A	N/A	551.0	551.0
59614	398.5	327.5	N/A	N/A	42.0	42.0
59618	792.5	793.5	N/A	N/A	587.0	587.0
59622	451.5	367.5	N/A	N/A	78.0	78.0
90791	90.0	90.0	-	-	-	-
90792	90.0	90.0	-	-	-	-
90832	45.0	45.0	-	-	-	-
90834	60.0	60.0	-	-	-	-
90837	75.0	75.0	-	-	-	-
90951	274.0	365.0	60.0	34.0	60.0	60.0
90954	240.0	240.0	60.0	-	60.0	60.0
90955	198.0	227.0	60.0	55.0	60.0	60.0
90956	148.0	163.0	60.0	59.0	60.0	60.0
90957	253.0	310.0	60.0	53.0	60.0	60.0
90958	183.0	212.0	60.0	55.0	60.0	60.0
90959	133.0	148.0	60.0	59.0	60.0	60.0
90960	128.0	156.0	60.0	54.0	60.0	60.0
90961	113.0	134.0	60.0	54.0	60.0	60.0
90962	63.0	70.0	60.0	58.0	60.0	60.0
90963	258.0	287.0	60.0	55.0	60.0	60.0
90964	233.0	255.0	60.0	57.0	60.0	60.0
90965	218.0	240.0	60.0	57.0	60.0	60.0
90966	75.0	96.0	60.0	54.0	60.0	60.0
90968	7.8	8.5	2.0	1.9	2.0	2.0
90969	7.3	8.0	2.0	1.9	2.0	2.0
90970	2.5	3.2	2.0	1.8	2.0	2.0
92521	110.0	110.0	-	-	N/A	N/A
92522	85.0	85.0	-	-	N/A	N/A
92523	157.0	157.0	-	-	N/A	N/A
92524	75.0	75.0	-	-	N/A	N/A
97161	55.0	55.0	41.0	41.0	N/A	N/A
97162	55.0	55.0	41.0	41.0	N/A	N/A
97163	55.0	55.0	41.0	41.0	N/A	N/A
97164	35.0	35.0	34.0	34.0	N/A	N/A
97165	65.0	65.0	32.0	32.0	N/A	N/A
97166	65.0	65.0	32.0	32.0	N/A	N/A
97167	65.0	65.0	32.0	32.0	N/A	N/A
97168	45.0	45.0	26.0	26.0	N/A	N/A
99201	17.0	N/A	26.0	N/A	-	-
99202	22.0	20.0	39.0	34.0	-	-
99203	29.0	35.0	51.0	43.0	-	-
99204	45.0	60.0	62.0	54.0	-	-
99205	67.0	88.0	71.0	67.0	-	-

HCPCS	Phys. Time (Minutes) – CY 2020	Phys. Time (Minutes) – CY 2021 Final	NF Clinical Staff Time (Minutes) - CY2020	NF Clinical Staff Time (Minutes) – CY 2021 Final	Fac. Clinical Staff Time (Minutes) – CY 2020	Fac. Clinical Staff Time (Minutes) – CY 2021 Final
99211	7.0	7.0	19.0	17.0	-	-
99212	16.0	16.0	28.0	28.0	-	-
99213	23.0	30.0	36.0	36.0	-	-
99214	40.0	47.0	53.0	51.0	-	-
99215	55.0	70.0	63.0	62.0	-	-
99283	30.0	30.0	N/A	N/A	-	-
99284	40.0	40.0	N/A	N/A	-	-
99285	55.0	55.0	N/A	N/A	-	-
99483	85.0	85.0	92.0	92.0	-	-
99492	40.0	40.0	85.0	85.0	-	-
99493	36.0	36.0	60.0	60.0	-	-
99495	47.0	54.0	107.0	105.0	-	-
99496	60.0	75.0	145.0	144.0	-	-
G0402	0.2	45.0	62.0	54.0	-	-
G0438	0.2	45.0	62.0	54.0	-	-
G0439	0.4	1.9	40.0	0.4	51.0	40.0

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6. Emergency Department Visits

We have revalued the ED visit codes (CPT codes 99281–99285, see Table 25 for long descriptors) under the PFS three times: In 1997, 2007, and most recently in 2020 as part of the misvalued code initiative. In the past, consistent with AMA RUC recommendations, we revalued these services such that the values of levels 1 through 3 of the ED visits were equal to levels 1 through 3 new patient office/outpatient E/M visits, and the levels 4 and 5 ED visits were valued higher than the levels 4 and 5 new patient office/outpatient E/M visits to reflect higher typical intensity. Also in the CY 2018 PFS final rule, we finalized a proposal to nominate all five ED visit codes as potentially misvalued, based on information suggesting that the work RVUs for ED visits may not appropriately reflect the full resources involved in furnishing these services. Specifically, some stakeholders expressed concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus EDs, where ED visits are furnished (82 FR 53018). Accordingly, the AMA RUC resurveyed and reviewed these five codes for the April 2018 RUC meeting, and provided a recommendation to CMS for consideration in CY 2020 rulemaking. In the CY 2020 PFS final rule (84 FR 62796), we finalized the RUC-recommended increases to the work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285. The RUC did not recommend, and we did not finalize, any change in direct PE inputs for the codes in this family. We note that the AMA RUC submitted these recommended values to CMS prior to the submission of the RUC-recommended revaluation of the office/outpatient E/M visit code family.

In response to our proposal to accept the RUC-recommended values for the ED visits, and to our comment solicitation in CY 2020 PFS proposed rule regarding whether we should revalue certain services commensurate with increases to the office/outpatient E/M visits (84 FR 62859 through 62860), a commenter submitted a public comment stating that relativity between the ED visits and office/outpatient E/M visits should be maintained, and submitting a specific recommendation for CPT codes 99283–99285 that was higher than the RUC-recommended values. The commenter stated we should preserve the relationship between the ED and office/outpatient E/M visit code sets that was established in prior years and that they believe would have likely been maintained had the office/outpatient E/M visits been reviewed prior to the ED visits. In order to avoid the rank order anomaly whereby an ED visit would be valued lower than the analogous office/outpatient E/M visit in CY 2021, we proposed in this current rulemaking cycle to adopt the values recommended by this commenter, and as shown in Table 25. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal. This commenter stated that levels 1–3 ED visits should remain the same as the levels 1–3 new patient office visits, and that levels 4–5 ED visits should have a higher value than the corresponding office visits due to the complexity of the patients requiring that level of emergency care.

Response: We are finalizing as proposed, as shown in Table 25, in order to avoid a rank order anomaly. We understand that the AMA workgroup on E/M services is continuing to consider further changes in coding and interpretive guidance for visit level selection for all of the E/M visit code sets other than the office/outpatient E/M visits, in light of the recent changes for office/outpatient visits. We will continue to stay abreast of this important work and continue considering the appropriate valuation of ED and other E/M visit code sets in light of any future changes in this arena by the CPT Editorial Panel and the AMA RUC.

Comment: Several commenters requested that we consider the nursing facility visits (CPT codes 99304–99318), domiciliary visits (CPT codes 99324–99337), and home visits (CPT codes 99341–99350) to be analogous to the office/outpatient E/M visits, noting that they are identical in every way except the setting of care and vulnerability of

the patient population. These commenters indicated that the CPT Editorial Panel and the AMA RUC will be reviewing these code sets in the near future, and their primary concern was to maintain access to care until this review is complete. Accordingly, these commenters recommended that we increase the work RVUs for these services to the extent necessary to maintain the payment rate for these codes at 2020 levels. These commenters provided an estimate of the revised work RVUs necessary to achieve this as a temporary measure, stating that due to relatively low service volume, these changes would not negatively impact the conversion factor.

Response: We did not propose to treat and revalue nursing facility visits, domiciliary visits and home visits as analogous to office/outpatient E/M visits. We do not agree with the commenters' assertions that these visits are identical to the office/outpatient E/M visit codes. The setting of care means that these visits involve different resources. In particular, skilled nursing facility (SNF) visits are reported using the nursing facility visit codes, rendering them substantially different from office/outpatient visits. For these reasons, we do not believe the commenters' requested changes to values for nursing facility visits, domiciliary visits, and home visits would be appropriate at this time. Additionally, we understand that the AMA workgroup on E/M services is continuing to consider further changes in coding and interpretive guidance for visit level selection for all of the E/M visit code sets other than the office/outpatient E/M visits, in light of the forthcoming changes for office/outpatient visits. We will continue to stay abreast of this important work and consider the appropriate valuation of home, domiciliary, nursing facility and other E/M visit code sets in light of any future changes in this arena by the CPT Editorial Panel and the AMA RUC.

7. Therapy Evaluations

There are a number of services paid under the PFS that are similar in many respects to the office/outpatient E/M visit code set, but do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits. Some codes inherently include work associated with assessment and work associated with management, similar to the work included in the office/outpatient E/M visits, which involve time spent face-to-face assessing and treating the patient. These services include therapy evaluation services and psychiatric diagnostic evaluation services. The practitioners who furnish these services are prohibited by CMS from billing E/M services due to the limitations of their Medicare benefit categories. As such, the CPT Editorial Panel has created specific coding to describe the services furnished by these practitioners. Although these services are billed using specific, distinct codes relating to therapy evaluations and psychiatric diagnostic evaluations, we believe that a significant portion of the overall work in the codes is for assessment and management of patients, as it is for the office/outpatient E/M visit codes.

Therefore, we proposed to adjust the work RVUs for these services based on a broad-based estimate of the overall change in the work associated with assessment and management to mirror the overall increase in the work of the office/outpatient E/M visits. We calculated this adjustment based on a volume-weighted average of the increases to the office/outpatient E/M visit work RVUs from CY 2020 to CY 2021. Details on this calculation are available as a public use file on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices*. We proposed to apply that percentage increase, which we estimated to be approximately 28 percent, to the work RVUs for the therapy evaluation and psychiatric diagnostic evaluation services codes. We noted that we believe that it is important to the relativity of the PFS to revalue these services to reflect the overall increase in value associated with spending time assessing and managing patients, as reflected in the changes to work values for the office/outpatient E/M visits, particularly in recognition of the value of the clinicians' time which is spent treating a growing number of patients with greater needs and multiple medical conditions. We recognized that this is not the methodology typically used to value services under the PFS and solicited comment on potential alternative methodologies or specific values for these services, particularly about whether commenters believe it would be better to develop values using comparator codes from the office/outpatient E/M visit code set, and if so, why.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal to adjust the work RVUs for outpatient therapy evaluations and to consider alternative approaches submitted by stakeholders in future rulemaking that may better reflect the true values. Many commenters urged us to implement similar increases to the work RVUs of additional therapy services, including CPT codes 97140 (*Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes*), 97537 (*Community/work reintegration training (eg, shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes*), 97542 (*Wheelchair management (eg, assessment, fitting, training), each 15 minutes*), 97760 (*Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes*), 97761 (*Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes*), 97763 (*Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes*), 97597 (*Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less*), 97598 (*Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)*), 97750 (*Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes*), and 97755 (*Assistive technology assessment (eg, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility),*

direct one-on-one contact, with written report, each 15 minutes). These commenters stated that these services also involve assessment and management, and thus, are analogous to office/outpatient E/M visit codes.

Response: In the proposed rule, we discussed that these evaluations contained types of work, specifically time spent assessing and managing patients, that is similar to the work described by the office/outpatient E/M visit code set. We stated that the increase in value associated with the office/outpatient E/M visits reflected the changes to work values, particularly in recognition of the value of the clinicians' time spent treating a growing number of patients with greater needs and multiple medical conditions, that could also apply to physical therapy, occupational therapy, and speech language pathology evaluations. The CPT codes identified by commenters involve work that is not similar to that captured by the office/outpatient E/M codes, such as various types of therapeutic treatment. Therefore, we do not believe it would be appropriate to adjust the values of these codes to reflect the changes in valuation for the office/outpatient E/M codes.

Comment: Some commenters did not support our proposal to implement the proposed increases to these therapy codes, stating that it will amplify a previous misvaluation by CMS for codes that do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits. According to the commenters, these therapy codes were originally misvalued when CMS finalized a single RVU of 1.20 for all three codes rather than the RUC-recommended work RVUs, which created an overvaluation in aggregate for these services.

Response: In the proposed rule, we discussed our rationale for proposing to increase the values of these services relative to the increased values for the office/outpatient E/M visit code set. If the commenters believe the therapy codes are not appropriately valued, we note the public may nominate any code(s) as potentially misvalued through the usual misvalued code process or request that it be surveyed or valued through the AMA RUC.

After considering the public comments, we are finalizing the changes in values for the therapy codes as proposed.

8. Behavioral Healthcare Services

The psychotherapy code set is divided into psychotherapy that can be furnished as a standalone service and psychotherapy furnished in conjunction with an office/outpatient E/M visit. The standalone psychotherapy services are CPT codes 90832, 90834, and 90837 (See Table 25 for long descriptors). The CPT codes describing psychotherapy furnished in conjunction with an office/outpatient E/M visit are CPT codes 90833 (*Psychotherapy, 30 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*), 90836 (*Psychotherapy, 45 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*) and 90838 (*Psychotherapy, 60 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*). As the values for the office/outpatient E/M visits are increasing, there will necessarily be an increase in the overall value for psychotherapy furnished in conjunction with office/outpatient E/M visits. We believe that it is important, both in terms of supporting access to behavioral health services through appropriate payment and maintaining relativity within this code family, to increase the values for the standalone psychotherapy services to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the add-on psychotherapy services with equivalent times. For example, under the finalized revaluation of the office/outpatient E/M visits, the proportional work value of the standalone psychotherapy CPT code 90834 (*Psytx w pt 45 minutes*) would decrease relative to the combined work RVUs for CPT code 99214 (*Level 4 Office/outpatient visit est*) when billed with CPT code 90836 (*Psytx w pt w e/m 45 min*). The current combined work RVU for CPT code 99214 when reported with CPT code 90836 is 3.40 (1.90 + 1.50) and the current work RVU for CPT code 90834 is 2.0. With the revaluation of the office/outpatient E/M visits beginning for CY 2021, the combined work RVU for CPT codes 99214 and 90836 would be 3.82 (1.90 + 1.92), while the current work RVU for 90834 would remain at 2.0, resulting in a change to relativity between these services.

To maintain the current relativity, which we believe to be appropriate based on the proportionate difference between these services, we are proposing to increase the work RVU for CPT code 90834 from 2.00 to 2.25 based on the marginal increase in work value for CPT code 99214 from CY 2020 to CY 2021. Similarly, for CPT code 90832, which describes 30 minutes of psychotherapy, we proposed to increase its work RVU based on the increase to CPT code 99213, which is most commonly billed with the 30 minutes of psychotherapy add-on, CPT code 90833. For CPT code 90837, which describes 60 minutes of psychotherapy, we propose to increase the work RVU based on the proportional increase to CPT codes 99214 and 90838, which is the office/outpatient E/M visit code most frequently billed with the 60 minutes of psychotherapy add-on. Table 25 provides a summary of the current and final RVUs for these services.

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TABLE 25: Current and Final Work RVUS for ED Visits, Therapy, and Psychotherapy Services

HCPCS Code	Long Descriptor	CY 2020 Work RVU	CY 2021 Final Work RVU
99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.	1.42	1.60
99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.	2.60	2.74
99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.	3.80	4.00
90791	Psychiatric diagnostic evaluation	3.00	3.84
90792	Psychiatric diagnostic evaluation with medical services	3.25	4.16
90832	Psychotherapy, 30 minutes with patient	1.50	1.70
90834	Psychotherapy, 45 minutes with patient	2.00	2.24
90837	Psychotherapy, 60 minutes with patient	3.00	3.31
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity	1.2	1.54

HCPCS Code	Long Descriptor	CY 2020 Work RVU	CY 2021 Final Work RVU
	limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.		
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.	0.75	0.96
97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed	0.75	0.96

HCPCS Code	Long Descriptor	CY 2020 Work RVU	CY 2021 Final Work RVU
	when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.		
92521	Evaluation of speech fluency (eg, stuttering, cluttering)	1.75	2.24
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);	1.5	1.92
92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)	3	3.84
92524	Behavioral and qualitative analysis of voice and resonance	1.5	1.92

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We received public comments on the Behavioral Healthcare services. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support this proposal, stating it relies on a flawed methodology; specifically, the stand-alone codes, which were established for NPPs to report psychotherapy services, were not valued based on a comparison to the psychotherapy codes delivered in conjunction with an E/M (codes 90833, 90836 and 90838). These commenters noted that these are two distinct codes sets: one for NPPs and one for physicians/QHPs representing different levels of similar work. CMS should compare psychotherapy to psychotherapy, not psychotherapy to psychotherapy plus E/M. Accordingly, these commenters did not support CMS's proposal to increase the values of 90832, 90834, and 90837 to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the add-on psychotherapy services with equivalent times.

Other commenters were concerned that the increases to some of the psychotherapy services will skew the relativity not only to the psychotherapy services provided along with an E/M service but to other services within the psychiatry section.

Some commenters supported increases for these services, but stated that commensurate relativity adjustments are needed for all Psychotherapy, Psychological and Neuropsychological Testing, and HBAI codes. Specifically, these commenters recommended proportionate increases to CPT codes 90791 (*Psychiatric diagnostic evaluation*), 90839 (*Psychotherapy for crisis; first 60 minutes*), 90845 (*Psychoanalysis*), 90847 (*Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes*), and 90853 (*Group psychotherapy (other than of a multiple-family group)*), as well as to the HBAI code set (CPT codes 96156 (*Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)*), 96158 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*), 96159 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)*), and 97170 (*Athletic training evaluation, moderate complexity, requiring these components: A medical history and physical activity profile with 1–2 comorbidities that affect physical activity; An examination of affected body area and other symptomatic or related systems addressing a total of 3 or more elements from any of the following: body structures, physical activity, and/or participation deficiencies; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.*); and to the Psychological and Neuropsychological Testing code set (CPT codes 96116 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour*), 96121 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)*), 96130 (*Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*), 96131 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*), 96132 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*), 96133 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for*

primary procedure)), 96136 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes*), 96137 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*), 96138 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes*), 96139 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*), and 96146 (*Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only)*), all of which were valued relative to the family of psychotherapy services through the AMA RUC process.

Response: We identified standalone psychotherapy services for adjustment to preserve the relative value of these services to psychotherapy services performed in conjunction with an office/outpatient E/M. We disagree with commenters who stated that, as the standalone psychotherapy codes were purposefully and appropriately valued without reference to the values of E/M services, we should not consider updating these values to retain relativity between standalone psychotherapy and psychotherapy billed in conjunction with an office/outpatient E/M. With regard to requests from commenters to adjust values of additional services, we continue to believe that our rationale for proposing proportionate adjustments to the stand-alone psychotherapy services does not apply to the wider psychotherapy code set. We believe that the value of stand-alone psychotherapy is analogous to the values of the office/outpatient E/M visit codes due to the nature of the work performed. These services describe E/M-type services furnished in some circumstances by practitioners who would not bill E/M services. Health and Behavior Assessment and Intervention and Psychological and Neuropsychological Testing are fundamentally different in that they describe testing services.

Having considered the public comments we received, we are finalizing our proposed increases to the values of CPT codes 90832, 90834, and 90837.

9. Ophthalmological Services

Prior to the CY 2021 PFS proposed rule, we had received a request to revalue the following ophthalmological services that we did not propose to revalue:

- CPT code 92002: *Ophthalmological services: Medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient.*
- CPT code 92004: *Ophthalmological services: Medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits.*
- CPT code 92012: *Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient.*
- CPT code 92014: *Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits.*

We did not propose to revalue these services because they are not sufficiently analogous to the office/outpatient E/M visit codes. While these ophthalmological services have historically been valued relative to office/outpatient E/M visits, the AMA RUC has not reviewed them since 2007. Two of these ophthalmological services can include more than one visit, and the number of visits included in the package is uncertain and therefore not so closely tied to office and outpatient E/M services, which describe a single visit. In addition, starting in 2021, the office/outpatient E/M visit codes will be substantially redefined to allow time or medical decision-making for code level selection—concepts that do not apply to the ophthalmological visits which rely on criteria specific to evaluation, examination, specified technical procedures, and treatment of ocular conditions for purposes of level selection.[8] The number of levels is different within the two code sets, and the number of levels has changed for office/outpatient E/M visits. Given the revised code set and framework for level selection for office/outpatient E/M visits, the level of office/outpatient E/M visits to which the ophthalmological visits might be analogous is unclear. We also noted that we are aware that ophthalmologists report office/outpatient E/M visits as well these ophthalmologic-specific evaluation codes. The relationship between the two separate code sets and the reason for maintaining and using both of them is unclear.

In the proposed rule, we also noted that the four ophthalmological evaluation codes are frequently reported with modifier -25 (significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service), as are ED visits. For the ophthalmological evaluations and ED visits, approximately one-third of the time, the same-day E/M service is a zero-day global surgical code, whereas for the office/outpatient E/M visits, approximately one-fifth of the same-day claims are for zero-day global services. We noted that we believe that visit/evaluation codes furnished the same day as a minor procedure are not closely analogous to stand-alone office/outpatient E/M visits. As we discussed in prior rulemaking, we continue to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing office/outpatient E/M visits to warrant different payment (see, for example, the CY 2019 PFS final rule, 83 FR 59639). As we were still in process of analyzing these data, we solicited public comment on whether visits/evaluations that are furnished frequently with same-day procedures should be revalued commensurate with increases to the office/outpatient E/M visits, or whether they are substantially different enough to warrant independent valuation. We noted further that the stand-alone psychotherapy services would be revalued to maintain relativity with the psychotherapy services that can be performed in conjunction with an E/M visit. Stand-alone psychotherapy services cannot be billed with office/outpatient E/M visits while ophthalmological visits can, as well as with a separate procedure.

We received public comments on our decision not to propose new valuations for these ophthalmological services. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that concurrent billing with same-day, zero-day global procedures should not be factor in whether or not we increase the ophthalmology evaluation codes commensurate with office/outpatient E/M visits. The commenter stated that the intravitreal injection code accounting for much of the volume of these zero-day global procedures (CPT code 67028) does not include an office examination. The commenter also stated that resource

[8] CPT Codebook pp. 656–7.

duplication between the same-day services is accounted for in the RUC valuation that reduces the pre- and post-times for the procedure if it is furnished more than 50 percent of the time with an E/M visit or eye evaluation. Another commenter noted that the AWV can be reported the same day as an office/outpatient E/M visit, and urged CMS not to treat primary care and surgical specialties differentially.

Response: We continue to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone office/outpatient E/M visits to warrant different payment. However, we understand that such a policy would apply to ophthalmology evaluations, ED visits and other services. We believe the better way to account for duplicative resources across the fee schedule would be a payment reduction along the lines of a multiple procedure payment reduction for services reported using modifier −25.We will continue to consider implementing a policy to address this issue. We note that the policy that we proposed and declined to finalize for CY 2019 would have applied a multiple ''procedure'' payment adjustment to two visits reported the same day, as well as a visit with a minor procedure. We are also considering whether the office/outpatient visit complexity HCPCS add-on code GPC1X should be reported when the visit is reported with modifier −25 (see section II.F.2.c. of this final rule).

Comment: One commenter stated that while the ophthalmological evaluations have not been recently revalued by the AMA RUC, the AWV has never been reviewed by the RUC.

Response: We discuss above our rationale for considering the AWV as an analogous service to the office/outpatient E/M services. Regarding consideration of the AWV by the RUC, we note that the AWV is a service described by a code that is unique to Medicare and not applicable for other payers. As such, we do not see a need for the RUC to review this service, but if it did, we would consider its recommendations through our usual rulemaking process. As discussed above, our decision to consider a given code(s) as analogous to the office/outpatient E/M visits is not based on any single factor, but rather takes into account various applicable factors. The public may nominate any code(s) as potentially misvalued through the usual misvalued code process or request that it be surveyed or valued through the AMA RUC.

Comment: The same commenter stated that all four of the ophthalmology codes are valued based on a single visit on the date of encounter, and the level of that visit is directly compared to levels of office E/M codes. The commenter also stated that while the ophthalmological codes do not rely on time to select visit level, both code sets will be able to use MDM to select visit level, and that MDM was a basis for prior comparison to office/outpatient E/M visit codes.

Response: We continue to note that two of these ophthalmological services can include more than one visit, and therefore, the resource costs are not as closely tied to office and outpatient E/M visits (that describe a single visit) as the AWV/IPPE, TCM, cognitive impairment and other codes we are considering to be analogous to office/outpatient E/M visits. We disagree that reliance on time and differences in MDM interpretive guidance are not substantial differences between the 2021 office/outpatient E/M visit codes and the ophthalmology evaluation codes. Also, we continue to believe that the corresponding visit levels for the two code sets are not clear, such that the level of office/outpatient E/M visits to which the ophthalmological visits might be analogous is not apparent. We continue to note that ophthalmologists report office/outpatient E/M visits as well these ophthalmologic-specific evaluation codes. The relationship between the two separate code sets and the reason for maintaining and using both of them remains unclear. Having considered the public comments we received, we are finalizing our decision not to revalue the ophthalmological evaluations commensurate with the changes to the office/outpatient EM visit valuations for 2021. Stakeholders may still request review of these services by the RUC or through our misvalued code initiative.

c. Comment Solicitation on the Definition of HCPCS Add-On Code G2211

Although we believe that the RUC-recommended values for the revised office/outpatient E/M visit codes will more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, we continue to believe that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. Therefore, in the CY 2020 PFS final rule (84 FR 62856), we finalized the HCPCS add-on code G2211 (which replaces temporary HCPCS add-on code GPC1X) and which describes the ''visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition.'' We stated that we were not restricting billing based on specialty, but that we did assume that certain specialties furnished these types of visits more than others.

Since the publication of the CY 2020 PFS final rule, some specialty societies have stated that our definition of this service, as articulated in the code descriptor and the associated preamble discussion, is unclear. For example, some stakeholders have suggested that HCPCS add-on code G2211, as currently described, could be applicable for every office/outpatient E/M visit. They have also expressed concerns regarding our utilization assumptions, since we assumed that specialties that predominantly furnish the kind of care described by the code would bill it with every visit. Therefore, we solicited public comments providing additional, more specific information regarding what aspects of the definition of HCPCS add-on code G2211 are unclear, how we might address those concerns, and how we might refine our utilization assumptions for the code.

We continue to believe that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that result in a comprehensive, longitudinal, and continuous relationship with the patient and involves delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set. We believe the inclusion of HCPCS add-on code G2211 appropriately recognizes the resources involved when practitioners furnish services that are best-suited to patients' ongoing care needs and potentially evolving illness. We also believe the work reflected in HCPCS add-on code G2211 is inherently distinct from existing coding that describes preventive and care management services. For example, the AWV describes and pays for a static annual health assessment rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Similarly, TCM service codes are focused on care management for 30 days

following a discharge rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Chronic care management and principal care management service codes are limited to patients with chronic condition(s). Under chronic care management codes, patients have two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, whereas principal care management services are for patients who have a single high-risk disease of sufficient severity to place the patient at risk of hospitalization or have been the cause of recent hospitalization. In contrast, we believe HCPCS add-on code G2211 reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time. For example, in the context of primary care, HCPCS add-on code G2211 could recognize the resources inherent in holistic, patient-centered care that integrates the treatment of illness or injury, management of acute and chronic health conditions, and coordination of specialty care in a collaborative relationship with the clinical care team. In the context of specialty care, HCPCS add-on code G2211 could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals. In both examples, HCPCS add-on code G2211 reflects the time, intensity, and PE associated with providing services that result in care that is personalized to the patient. Finally, we believe that the HCPCS add-on code G2211 could bolster the efforts of practitioners in rural communities, including NPPs, to deliver the comprehensive and longitudinal care that HCPCS add-on code G2211 describes.

We received public comments on our comment solicitation related to HCPCS add-on code G2211. The following is a summary of the comments we received and our responses.

Comment: Many commenters who rely upon office/outpatient E/M visits to report the majority of their services continued to be supportive of HCPCS add-on code G2211. These commenters agreed with CMS that the revised office/outpatient E/M visit codes do not adequately describe or reflect the resources associated with primary care and certain types of specialty visits and agreed that the code descriptor fits its intended purpose, is well-defined, and did not allude to specific specialties. Other commenters disagreed, maintaining that the definition of HCPCS add-on code G2211 is unclear. Some commenters stated that it appeared that HCPCS add-on code G2211 could be reported with most office/outpatient E/M visits and questioned whether widespread use accurately captured genuine longitudinal care relationships. These commenters requested that CMS provide clinical examples for appropriate reporting. Other commenters provided CMS with suggested clinical examples for when HCPCS add-on code G2211 could be reported. For example, some commenters stated that HCPCS add-on code G2211 would capture additional work by the reporting practitioner to treat patients with disease processes that require active monitoring outside of office/outpatient E/M visits and are not captured in current coding. This work could include oversight of medication refills; evaluating appropriateness of current and new medications, including those initially prescribed by other practitioners; and conducting medication-related monitoring and safety activities when these activities are not part of a visit. It could also include review of lab and imaging reports, including those requested by another practitioner, that fall outside the timeframe of an office/outpatient E/M visit, and do not necessitate a new visit. Finally, some commenters suggested that CMS describe circumstances when HCPCS add-on code G2211 would not be reported with an office/outpatient E/M visit.

Response: We appreciate all of the feedback from the commenters. We believe that HCPCS add-on code G2211 captures the work by the reporting practitioner for many office/outpatient E/M visits that is not accounted for in the valuation of the primary office/outpatient E/M visit code. In the context of primary care, a clinical example for the use of HCPCS add-on code G2211 could be: a 68 year-old woman with progressive congestive heart failure (CHF), diabetes, and gout, on multiple medications, who presents to her physician for an established patient visit. The clinician discusses the patient's current health issues, which includes confirmation that her CHF symptoms have remained stable over the past 3 months. She also denies symptoms to suggest hyper- or hypoglycemia, but does note ongoing pain in her right wrist and knee. The clinician adjusts the dosage of some of the patient's medications, instructs the patient to take acetaminophen for her joint pain, and orders laboratory tests to assess glycemic control, metabolic status, and kidney function. The practitioner also discusses age appropriate prevention with the patient and orders a pneumonia vaccination and screening colonoscopy. In this clinical example, the practitioner is serving as a focal point for the patient's care, addressing the broad scope of the patient's health care needs, by furnishing care for some or all of the patient's conditions across a spectrum of diagnoses and organ systems with consistency and continuity over time.

Moreover, we believe that similar visits might be furnished by other specialists when management of a particular disease condition(s) is ongoing or serves as a focal point of care for a patient's overall health needs over a period of time. In other words, when care by specialists for a particular disease condition(s) is consistent and continuous over long periods of time, the work associated with those visits is similar to the kind of work described above.

In contrast, there are many visits with new or established patients where HCPCS add-on code G2211 would not be appropriately reported, such as when the care furnished during the office/outpatient E/M visit is provided by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature, such as a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus; for counseling related to seasonal allergies, initial onset gastroesophageal reflux disease; treatment for a fracture; and where comorbidities are either not present or not addressed, and/or and when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time. Reporting the add-on code with these types of visits would be inconsistent with the code

descriptor, which describes care that is a continuing focal point and/or part of ongoing care. We also would not expect that HCPCS add-on code G2211 would be reported when the office/outpatient E/M is reported with a payment modifier, such as the modifier -25 described in the ophthalmological services section above. It seems likely that visits reported with payment modifiers have resources that are sufficiently distinct from stand-alone office/outpatient E/M visits. We will be considering this issue to inform potential future rulemaking.

Comment: Some commenters suggested that a lack of clarity in the definition of HCPCS add-on code G2211 poses program integrity challenges for CMS. They pointed out that CMS has offered no information about how appropriate use will be determined or what documentation will be expected. Some commenters requested guidance on what documentation would need to be included when HCPCS add-on code G2211 is reported.

Response: We appreciate the concerns raised by the commenters. Since HCPCS add-on code G2211 is a new service paid under the PFS, we plan to monitor utilization for appropriate use of the add-on code, which could inform additional efforts to refine the code descriptor, or provide further guidance, as appropriate. With respect to documentation, we are considering an approach to minimize burden similar to what we finalized in the CY 2019 PFS final rule (83 FR 59560) for HCPCS add-on codes GPC1X and GCG0X. In that rule, we discussed that we would expect that information included in the medical record or in the claims history for a patient/practitioner combination, such as diagnoses, the practitioner's assessment and plan for the visit, and/or other service codes billed could serve as supporting documentation. We believe Medicare claims data could be a useful gauge of appropriate use of the code. For example, when billing practitioners are separately reporting care management services for particular beneficiaries, the G2211 add-on service would be appropriately reported with their visits, as claims for these care management services could indicate an ongoing, continuous relationship with the patient. Likewise, patients returning to the same practitioner for routine preventive services would indicate that the practitioner has taken responsibility for ongoing medical needs for that patient with consistency and continuity over time. In contrast, an annual visit for ophthalmologic care, or a single episode of dermatologic care—even when several services are billed over a few months—would not suggest ongoing care provided with consistency and continuity over time and would suggest an inappropriate use of the code, were it to be billed with such visits. Additionally, to provide evidence of the ongoing relationship between the patient and practitioner, it is possible that use of patient relationship codes that were established under MACRA and finalized in the CY 2018 PFS (82 FR 53234) could be further example of evidence in the claims record to support the use of HCPCS add-on code G2211. These codes are Level II HCPCS modifiers that help define and distinguish the relationship and responsibility of a clinician with a patient at the time of furnishing an item or service, facilitate the attribution of patients and episodes to one or more clinicians, and to allow clinicians to self-identify their patient relationships.

Comment: Some commenters recommended that HCPCS add-on code G2211 should be available for both new and established patients. A few other commenters noted that the code descriptor for HCPCS add-on code G2211 had one version of the long descriptor in this section of the proposed rule and another version of the long descriptor in section II.D. Another commenter recommended an edit to the code descriptor to eliminate the comma between ''single'' and ''serious.''

Response: We are confirming that HCPCS add-on code G2211 can be reported for both new and established patients. With respect to the version of the long descriptor, the version used in section II.D of the proposed rule was a drafting error. We regret the error and have corrected the description in section II.D of this final rule. While we appreciate the suggested edit to the code descriptor, we did not believe it offered additional clarification. To improve the clarity of the code descriptor, we are finalizing a refinement for the code description to clarify that the code applies to a single condition that is serious, rather than any single condition. We are inserting the word ''condition'' after ''single, serious''. The revised descriptor reads as follows, ''*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).*''

Comment: A few commenters recommended that CMS allow HCPCS add-on code G2211 to be reported with E/M services furnished in domiciliary care settings.

Response: We reiterate that we are implementing HCPCS add-on code G2211 because we believe the that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits and as such, does not include other types of E/M visits. As the CPT Editorial Panel, the AMA RUC and CMS consider future changes to other E/M visit code sets, we will consider this issue in that context.

Comment: Other commenters expressed continued concern regarding the necessity of HCPCS add-on code G2211 entirely and recommended that CMS withdraw the code. A few stated that HCPCS add-on code G2211 is not a separately identifiable service given the changes to the office/outpatient E/M visit code set and that it may be duplicative to care management services, such as TCM or CCM.

Response: As we stated in the proposed rule, we continue to believe that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that result in a comprehensive, longitudinal, and continuous relationship with the patient and involves delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set. We also reiterate what we stated in the proposed rule that HCPCS add-on code G2211 is inherently distinct from coding that describes care management services. For example, TCM service codes are focused on care management for 30 days following a discharge rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Chronic care management and principal care management service codes are limited to patients with chronic condition(s). Under chronic care management codes, patients have two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, whereas principal care management services are for patients who have a single high-risk disease of sufficient severity to place the patient at risk of hospitalization or have been the cause of recent hospitalization. In contrast, we believe HCPCS add-on code G2211 reflects the time, intensity,

and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time.

Comment: Many commenters expressed concerns about the utilization assumptions for HCPCS add-on code G2211. Commenters stated that, in the CY 2020 PFS rulemaking cycle, CMS appeared to assume that HCPCS add-on code G2211 would be reported with 50 percent of all office/outpatient E/M visits; and in the CY 2021 PFS proposed rule, CMS appeared to assume that HCPCS add-on code G2211 would be reported with 75 percent of all office/outpatient E/M visits. Commenters noted that this additional utilization further contributed to the redistributive effect of the budget neutrality adjustment related to revaluing the office/outpatient visit codes. The AMA RUC requested that CMS publish the methodology used for the utilization assumptions in the CY 2021 PFS proposed rule prior to HCPCS add-on code G2211's implementation.

Response: In the CY 2020 PFS rulemaking cycle, we proposed and finalized that HCPCS add-on code G2211 would be billed with every level of an office/outpatient E/M visit. We assumed that specialties that rely on office/outpatient E/M visit coding to report the majority of their services would be most likely to report HCPCS add-on code G2211 with every office/outpatient E/M visit they reported and we did not restrict billing to any particular specialty or group of specialties. We published the utilization estimates for HCPCS add-on code G2211 in the CY 2020 PFS final rule in this public use file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-EM-Add-on-Code.zip*.

In the CY 2021 PFS proposed rule, we continued to assume that the specialties listed in the aforementioned public use file would report HCPCS add-on code G2211 with all of their office/outpatient E/M visits. As part of updating our data sources from CY 2018 to CY 2019 claims data for setting rates for the CY 2021 PFS proposed rule, we included modifier −25 utilization, meaning that we assumed that HCPCS add-on code G2211 would also be reported with office/outpatient E/M visits that were reported with a modifier −25. While this additional utilization was included in the budget neutrality calculations, we note that other proposals for CY 2021 also factor into the budget neutrality adjustment.

As we noted above, while we would not expect that HCPCS add-on code G2211 would be reported when the office/outpatient E/M visits is reported with a payment modifier, such as a modifier −25, we are not establishing any policies that prohibit reporting the add-on code under those circumstances. Thus, we will continue to include office/outpatient visits reported with a modifier −25 in our utilization assumptions for HCPCS code G2211 as part of calculating the budget neutrality adjustment for the policies we are finalizing in this rule. As we noted above, we would not expect HCPCS add-on code G2211 to be reported when the visit is reported with a modifier 2−5, and will consider whether to establish an explicit prohibition in future rulemaking. We continue to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone office/outpatient E/M visits to warrant different payment. We are also analyzing our data to determine if separately identifiable visits occurring on the same day as another visit have resources that are sufficiently distinct from the costs associated with furnishing stand-alone office/outpatient E/M visits to warrant different payment. We will consider these analyses to inform potential future rulemaking.

Comment: Many commenters recommended that CMS reexamine and lower utilization assumptions for HCPCS add-on code G2211. These commenters stated that utilization tends to be lower than expected in the first year of implementation and cited the initial low utilization of the TCM and CCM codes These commenters also stated that they expected adoption to be slow given the necessity for medical societies to educate their members about appropriate use, ongoing implementation of the revisions to the office/outpatient E/M visit code set, electronic health records integration, and the persistence of the COVID–19 pandemic in many parts of the country. They recommended that utilization in the initial year could be as low as 10 percent of reported office/outpatient E/M visits and could range as high as 25 percent of reported office/outpatient E/M visits. Other commenters recommended that CMS delay the implementation of HCPCS add-on code G2211, citing the expected budget neutrality offset.

Response: We acknowledge commenters' concerns that, given the necessity of medical societies to educate their members about appropriate use, ongoing implementation of the revisions to the office/outpatient E/M visit code set, electronic health records integration, and the persistence of the COVID–19 pandemic, practitioners that rely on office/outpatient E/M visits to report the majority of their services are not likely to report HCPCS add-on code G2211 with every office visit. However, we disagree the utilization will be as low as the 10 percent to 25 percent range as recommended by these commenters. We have not implemented any additional policies that restrict the billing of this code, and so we are assuming that utilization will be 90 percent of office/outpatient E/M visits instead of the 100 percent that we assumed in the proposed rule.

d. Prolonged Office/Outpatient E/M Visits (CPT Code 99417/HCPSC Code G2212)

We reviewed our final policy for 2021 regarding the reporting of prolonged office/outpatient E/M visits finalized in the CY 2020 PFS final rule (84 FR 62848 through 62850). To report these visits beginning in 2021, we finalized CPT code 99417 (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)*), which was referred to in our previous rules as temporary CPT code 99XXX. Under CPT prefatory language, CPT code 99417 should only be reported when time is used to select the visit level, and only time of the physician or qualified healthcare professional is counted. In the CY 2020 PFS final rule, we stated that our interpretation of revised CPT prefatory language and reporting instructions would mean that CPT code 99417 could be reported when the physician's (or NPP's) time is used for code level selection and the time for a level 5 office/outpatient E/M visit (the floor of the level 5 time range) is exceeded by 15 minutes or more on the date of service (84 FR 62848 through 62849). The intent of the CPT Editorial Panel was unclear because of the use of the terms ''total time'' and ''usual service'' in the CPT code descriptor (''*requiring total time with or without direct patient contact beyond the usual*

service.'') The term ''total time'' is unclear because office/outpatient E/M visits now represent a range of time, and ''total'' time could be interpreted as including prolonged time. Further, the term, ''usual service'' is undefined. There is no longer a typical time in the code descriptor that could be used as point of reference for when the ''usual time'' is exceeded for all practitioners, and there would be variation (as well as potential double counting of time) if applied at the individual practitioner level.

Having reviewed the policy we finalized last year, we believe that allowing reporting of CPT code 99417 after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. As a specific example, the time range for CPT code 99215 is 40–54 minutes. If the reporting practitioner spent 55 minutes of time, 14 of those minutes are included in the services described by CPT code 99215. Therefore, only 1 minute should be counted towards the additional 15 minutes needed to report CPT code 99417 and prolonged services should not be reportable as we finalized last year (see Table 33 of the CY 2020 PFS final rule (84 FR 62849)). Therefore, we proposed that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99417 could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. In Tables 26 and 27, we provided examples.

TABLE 26: Proposed Prolonged Office/Outpatient E/M Visit Reporting - New Patient

CPT Code(s)	Total Time Required for Reporting*
99205	60-74 minutes
99205 x 1 and 99417 x 1	89-103 minutes
99205 x 1 and 99417 x 2	104-118 minutes
99205 x 1 and 99417 x 3 or more for each additional 15 minutes.	119 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

TABLE 27: Proposed Prolonged Office/Outpatient E/M Visit Reporting – Established Patient

CPT Code(s)	Total Time Required for Reporting*
99215	40-54 minutes
99215 x 1 and 99417 x 1	69-83 minutes
99215 x 1 and 99417 x 2	84- 98 minutes
99215 x 1 and 99417 x 3 or more for each additional 15 minutes.	99 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

We received public comments on our proposal for use of CPT code 99417. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with our concerns about the lack of clarity in the code descriptor and the potential for double-counting time. Several other commenters disagreed with our proposal and recommended that CMS adopt the CPT code descriptors. These commenters stated that a change in policy by CMS could be confusing to practitioners and disruptive to the ongoing work of medical societies to educate practitioners about the use of these codes. Some commenters also stated the CPT Editorial Panel intended to apply the general CPT rule where practitioners can report a timed code once the midpoint is reached.

Response: In the CPT 2021 Professional Edition, CPT code 99417 is described as, ''*Prolonged office or other outpatient evaluation and management service(s) beyond the minimum required time of the primary procedure which has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)).*'' The terms ''total time'' and ''usual service'' continue to be unclear.

While we prefer to align with CPT coding to reduce potential confusion to practitioners, we continue to believe that CPT code 99417 as written is unclear and that allowing reporting of CPT code 99417 when the minimum required time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. It has not been our understanding that CPT intended for the midpoint time to suffice for reporting this code, and regardless, we did not previously finalize or intend to apply such a policy.

We continue to believe it is important for CMS and other stakeholders to know with certainty how much time practitioners spend furnishing office/outpatient E/M visits, in order to assess whether resources are accurately accounted for in their valuation. This is especially true once time can be used to select visit level, with new times established for this code set. To resolve the lack of clarity, we are finalizing our proposal regarding the time that may be counted for prolonged office/outpatient E/M visits; and to resolve the potential inconsistency of our policy with CPT code 99417, we are creating a new HCPCS code G2212 to be used when billing Medicare for this service instead of CPT code 99417, starting in 2021. HCPCS code G2212 is as follows,

''*Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services*) ''*(Do not report G2212 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416). (Do not report G2212 for any time unit less than 15 minutes))*''.''

We believe the creation of HCPCS code G2212 will serve to resolve the potential differences between Medicare and other interpretations of CPT rules, and better address questions we frequently receive about the required times and what time may be counted toward the required time to report prolonged office/outpatient E/M visits. We also note that we are not opposed in concept to reporting prolonged office/outpatient visit time on a date other than the visit. However, we continue to believe there should be a single prolonged code specific to office/outpatient E/M visits that encompasses all related time (see the CY 2020 PFS final rule for a more detailed discussion of this issue, (84 FR 62849 through 62850)). We will continue to stay abreast of any changes in CPT coding. The valuation for HCPCS code G2212 will be the same as for CPT code 99417.

G. Scope of Practice and Related Issues

We proposed several policies consistent with the President's E.O. 13890 on ''Protecting and Improving Medicare for Our Nation's Seniors'' to modify supervision and other requirements of the Medicare program that limit healthcare professionals from practicing at the top of their license (84 FR 53573, October 8, 2019, E.O. 13890). In December 2019, we requested feedback in response to part of this E.O. seeking the public's help in identifying additional Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or which limit health professionals from practicing at the top of their license (the request for feedback is available at *https://www.cms.gov/files/document/request-information-reducing-scope-practice-burden.pdf*). Through review of the feedback we received, we identified the proposed policies in section II.G. of the CY 2021 PFS proposed rule (85 FR 50139). We noted that we believe that physicians, NPPs, and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure, including education and training, to the extent permitted under the Medicare statute, as long as it is not likely to result in fraud, waste or abuse or create potential risks to beneficiary safety. The proposed policies may also help ensure an adequate number of clinicians, in addition to physicians, are able to furnish critical services including primary care services in areas where there is a shortage of physicians.[9] We noted that some of the proposals may also help alleviate the opioid crisis.

We solicited information about the number and names of states that have licensure or scope of practice laws in place, as well as any facility-specific policies, that would impact the ability of clinicians to exercise the flexibilities we proposed, to help us assess the potential impact of, or challenges for, the proposed changes. We noted that information about specific services (service-level information) would be especially helpful. We solicited public comment on whether applicable state laws, scope of practice, and facility policies would permit practitioners to exercise the proposed flexibilities if we were to adopt the proposed policies, and to what extent practitioners would be permitted to exercise the proposed flexibilities, such as for all diagnostic tests or only a subset.

We solicited information on these topics because the responses to our request for feedback issued in 2019 did not indicate the number of states that have more flexible scope of practice rules than our federal regulations, or whether facilities (such as hospitals or nursing facilities) have relevant policies that limit the ability of the impacted professionals to perform certain services. For example, if Medicare payment policy provided for payment of diagnostic tests supervised by NPPs, there may still be facility- or state-specific policies in place that limit NPPs' ability to supervise some or all diagnostic tests, and those limitations would inform the potential impact of changing our policy. While our proposed flexibility may increase the capacity and availability of practitioners who can supervise diagnostic tests, which would alleviate some of the demand on physicians as the only source to perform this particular function, we noted that we have not located information indicating the degree to which NPP scope of practice includes supervision of auxiliary staff, especially for the subset of services that are diagnostic tests. There is a wide range of diagnostic tests, from a simple strep throat swab to more sophisticated and/or invasive tests such as x-rays and cardiology procedures. We would need to understand the scope of practice for many types of auxiliary staff (some of whom are not licensed) who could potentially provide these tests under the supervision of an NPP, including RNs, LPNs, medical assistants, radiologic technicians, and many others. To the extent practice patterns change, there could be induced utilization that would increase costs, but this might be offset by reduced payment rates because direct payment to NPPs is at a lower rate than payment to physicians.

1. Teaching Physician and Resident Moonlighting Policies

a. Background

In the March 31st COVID–19 IFC (85 FR 19258 through 19261) and the May 8th COVID–19 IFC (85 FR 27587 through 27589), we implemented several policies on an interim final basis related to PFS payment for the services of teaching physicians involving residents and resident moonlighting during the PHE for COVID–19. In the proposed rule, we noted that we planned to address comments received on the IFCs for those policies that we made proposals or solicited comment on in the proposed rule when we published the PFS final rule.

b. Finalization of Interim Final Rule With Comment Period Provisions Related to Application of Teaching Physician and Moonlighting Regulations During the PHE for the COVID–19 Pandemic

We received public comments on the policies that we adopted on an interim basis in the Interim Final Rule with Comment Period provisions related to the Application of Teaching Physician and Moonlighting Regulations During the PHE for the COVID–19 Pandemic (85 FR 19258 through 19261). The following is a summary of the comments we received and our responses.

i. Virtual Presence of a Teaching Physician Using Audio/Video Real-Time Communications Technology

Comment: Commenters were generally supportive of the virtual presence policies in §§ 415.172, 415.174, 415.180, and 415.184 that we implemented on an interim basis during the PHE for COVID–19. Several commenters supported extending the flexibilities permanently, while several

[9] Zhang et al. Physician workforce in the United States of America: forecasting nationwide shortages. *Human Resources for Health* (2020); 18:8. Published online February 6, 2020 and available online at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7006215/*.

other commenters recommended continuing the policy temporarily through the end of the PHE for COVID–19, or for a period of time following the end of the PHE for COVID–19.

Response: We appreciate commenters' support for the virtual presence policies adopted on an interim basis during the PHE for COVID–19. After considering the comments, we are finalizing these policies for the duration of the PHE for COVID–19.

Comment: One commenter, in support of the virtual presence policies adopted on an interim basis during the PHE for COVID–19, recommended that CMS encourage residency programs, residency review committees, and ACGME to increase monitoring of clinical and educational work hour standards, acknowledge the impact of the changes to the teaching physician presence requirements on the residents and their optimal learning environment, and share additional information regarding how to best meet the need for reporting of information related to workload and growing service demands, patient safety, medical error, continuity of care, resident well-being and burnout, development of professionalism, resident learning outcomes, and preparation for independent practice as they relate to the use of teaching physician presence through real-time interactive audio and video technology.

Response: We do not believe it is CMS' role to regulate or monitor training outcomes or advocate on behalf of the residents themselves. Organizations representing the interests of residents and overseeing the actual operation of residency programs are in a better position to establish rules regarding the impact of virtual presence and involvement of teaching physicians on residency training outcomes.

Comment: One commenter noted that the GME community has learned many lessons during the pandemic, related to resident education and supervision. Consequently, the commenter believed that the GME community should be provided the flexibility to test new and better modalities of treatment and learning.

Response: We appreciate the commenter's support of our policies. As described previously, we are finalizing these policies for the duration of the PHE for COVID–19.

Comment: One commenter requested clarification of the definition of ''telecommunications,'' and asked whether supervision, in the context of a teaching institution, can be performed by telephone as opposed to a tablet or smartphone.

Response: The policy to allow a teaching physician to use audio/video real-time communications technology for purposes of furnishing care with a resident, and in the case of the primary care exception, directing, managing, and reviewing the care furnished by the resident, generally requires real-time direct observation (not mere availability) by the teaching physician through interactive, real-time audio and video technology, and does not include audio-only technology (for example, telephone without video).

Comment: Several commenters expressed support for the exclusion of surgical, high risk, interventional, endoscopic, or other complex procedures identified under § 415.172(a)(1), and anesthesia services under § 415.178 from the policy to allow the teaching physician to be present using audio/video real-time communications technology. One commenter recommended that the teaching physician virtual presence policy be permitted for CPT codes 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*), 31575 (*Laryngoscopy, flexible; diagnostic*), and 31579 (*Laryngoscopy, flexible or rigid telescopic, with stroboscopy*) performed through an endoscope.

Response: We continue to believe the requirement for the physical, in-person presence of the teaching physician during all key or critical portions of the procedure and immediately availability to furnish services during the entire service or procedure is necessary for patient safety given the risks associated with these services. In complex, high-risk procedures, including the endoscopic procedures associated with CPT codes 31231, 31575 and 31579, a patient's clinical status can quickly change. To permit payment under the PFS for such teaching physician services, we believe the services must be furnished with a certain level of personal oversight and involvement of the teaching physician who has the experience and judgment that is necessary for rapid on-site decision-making during these procedures. With respect to the procedures associated with CPT codes 31231, 31575 and 31579, we do not believe that virtual presence by a teaching physician would provide sufficient personal involvement and control over the service to warrant billing of the services under the PFS or allow for the rapid on-site decision-making that could be necessary during the procedures, which could pose an increased risk to patients.

ii. Virtual Presence of a Teaching Physician During Medicare Telehealth Services

Comment: Commenters were generally supportive of the policy adopted on an interim basis to allow payment under the PFS when residents furnish telehealth services to beneficiaries with the teaching physician present using audio/video real-time communications technology. In addition, several commenters supported extending the flexibility permanently.

Response: We appreciate commenters' support for the policy, adopted on an interim basis during the PHE for COVID–19, to allow payment under the PFS when residents furnish telehealth services to beneficiaries with the teaching physician present using interactive, audio/video real-time communications technology (excluding audio-only). After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

iii. Resident Moonlighting in the Inpatient Setting

Comment: Commenters were generally supportive of the policy under § 415.208 that we adopted on an interim basis during the PHE for COVID–19 to allow PFS payment for services provided by fully licensed residents that are not related to their approved GME program in the inpatient setting of a hospital in which they are training, provided that the conditions specified in § 415.208(b)(2)(i) through (iii) are met. Several commenters recommended that this policy be implemented permanently, and some other commenters recommended that the policy be implemented for the duration of the PHE only.

Response: We appreciate commenters' support for the moonlighting policy we adopted on an interim basis during the PHE for COVID–19. After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

iv. Primary Care Exception Policies

Comment: Commenters were generally supportive of the policy adopted on an interim basis under § 415.174 to expand the primary care exception to include all levels of office and outpatient E/M codes. Some commenters recommended that this policy be implemented permanently, and some other commenters recommended that the policy be implemented for the duration of the PHE for COVID–19 only.

Response: We appreciate commenters' support of the expansion of the primary care exception policy adopted on an interim basis during the PHE for COVID–19. After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

Comment: One commenter interpreted the policy described in § 415.174 to mean that the ''immediately available supervision'' requirement described in this section could be met by the teaching physician being ''immediately available'' via real-time audio/video technology.

Response: Subsequent to the publication of the March 31st COVID–19 IFC, the May 8th COVID–19 IFC amended § 415.174 to add a new paragraph (c) to allow that, on an interim basis for the duration of the PHE for COVID–19, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through virtual means via interactive, audio/video real-time communications technology (excluding audio-only).

v. Payment Under the PFS for Teaching Physician Services When Resident Under Quarantine

Comment: A commenter supported the interim policy for the duration of the PHE for COVID–19 to permit PFS payment for teaching physician services that do not require face-to-face patient care when the resident is furnishing such services while in quarantine when the teaching physician is present through audio/video real-time communications technology.

Response: We thank the commenter for their support. After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

c. Finalization of Interim Final Rule Provisions Related to Additional Flexibility Under the Teaching Physician Regulations

We received public comments on the policies that we adopted on an interim basis in the Interim Final Rule provisions related to Additional Flexibility Under the Teaching Physician Regulations (85 FR 27587 through 27589). The following is a summary of the comments we received and our responses.

i. Primary Care Exception Policies

*Comment: S*everal commenters supported the policy adopted on an interim basis to allow, under the primary care exception described in § 415.174(c), the teaching physician to direct the care furnished by the resident, and to review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology. Several commenters supported a temporary extension of the policy through the end of the PHE for COVID–19 or through 2021, while other commenters suggested a permanent extension of this flexibility.

Response: We appreciate the commenters' support of this policy during the PHE for COVID–19. After considering the comments and for the reasons discussed above, we are finalizing this policy for the duration of the PHE for COVID–19.

Comment: Some commenters requested clarification of the phrase ''interactive audio/visual real-time communication technology'' because CMS has used various terms when expressing technology requirements for remote supervision and in the context of teaching physician services, and because the presence of the slash mark in the phrase makes it unclear whether both audio and visual communication must be utilized to meet the requirement, or if one or the other is sufficient. One commenter also recommended that the phrase be revised to explicitly state that a real-time audio-only communication is sufficient in order to meet the regulations set forth in § 415.174(a)(3) for use of the primary care exception.

Response: While we believe our statements have been clear on this point, we clarify here that this virtual presence policy requires real-time observation (not mere availability) by the teaching physician through a contemporaneous, interactive combination of both audio and video communications technology, and does not include audio-only technology (for example, telephone without video). We note that we have used the ''audio/video'' formulation in our regulations, and that the ''slash'' should be read consistently to mean a synchronous, interactive, real-time combination of both audio and video technology, which would not include audio-only communications for any portion of the time of the furnished service.

Comment: Commenters were generally supportive of the policy adopted on an interim basis to allow Medicare to make payment to the teaching physician for additional services under the primary care exception, including all levels of office and outpatient E/M codes, audio-only telephone E/M services, transitional care management, and communication technology-based services. Several commenters supported a temporary extension of the policy through the end of the PHE for COVID–19 or through 2021, while other commenters suggested a permanent expansion of the services that residents could furnish under the primary care exception.

Response: We appreciate commenters' support of this policy during the PHE for COVID–19. After considering the comments, we are finalizing the policy for the duration of the PHE for COVID–19.

Comment: Several commenters thanked CMS for the clarification that Medicare may make payment under the PFS for teaching physician services when a resident furnishes services permitted under the primary care exception, including via telehealth, and the teaching physician can provide the necessary direction, management and review of the resident's services using interactive audio/video real-time communications technology.

Response: We appreciate the commenters' support for this policy during the PHE.

Comment: Several commenters supported the interim policy during the PHE for COVID–19 that the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on medical decision-making or time.

Response: We thank the commenters for their support of this policy during the PHE. This policy is similar to the policy that will apply to all office/outpatient E/M services beginning in 2021 under policies finalized in the CY 2020 PFS final rule and thus, we are not finalizing it.

d. Summary of Proposed Rule Provisions and Public Comments

i. Background

In the proposed rule, we considered whether the policies implemented on an interim basis in the March 31st COVID–19 IFC or the May 8th COVID–19 IFC should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comment. We noted that the public comments would assist us in identifying appropriate policies that we would consider in drafting the CY 2021 PFS final rule.

For teaching physicians, section 1842(b)(7)(A)(i)(I) of the Act specifies

that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought.

Regulations regarding PFS payment for teaching physician services and services of moonlighting residents are codified in 42 CFR part 415. In general, under § 415.170, payment is made under the PFS for services furnished in a teaching hospital setting if the services are personally furnished by a physician who is not a resident, or the services are furnished by a resident in the presence of a teaching physician, with exceptions as specified in subsequent regulatory provisions in part 415. Under § 415.172, if a resident participates in a service furnished in a teaching setting, PFS payment is made only if the teaching physician is present during the key portion of any service or procedure for which payment is sought. The regulation at § 415.180 states that, for the interpretation of diagnostic radiology and other diagnostic tests, PFS payment is made if the interpretation is performed or reviewed by a physician other than a resident. Under § 415.184, PFS payment is made for psychiatric services furnished under an approved graduate medical education (GME) program if the requirements of §§ 415.170 and 415.172 are met, except that the requirement for the presence of the teaching physician during psychiatric services in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

ii. Supervision of Residents in Teaching Settings Through Audio/Video Real-Time Communications Technology

In both the March 31st COVID–19 IFC (85 FR 19258 through 19261) and the May 8th COVID–19 IFC (85 FR 27587 through 27589), we adopted a policy on an interim basis during the PHE for COVID–19 that, under § 415.172, the requirement for the presence of a teaching physician during the key portion of the service furnished with the involvement of a resident can be met using audio/video real-time communications technology. In other words, the teaching physician must be present, either in person or virtually through audio/video real-time communications technology, during the key portion of the service. This policy generally requires real-time observation (not mere availability) by the teaching physician through audio and video technology, and does not include audio-only technology (for example, telephone without video). For the primary care exception under § 415.174(c), we adopted a policy on an interim final basis for the duration of the PHE for COVID–19 to allow the teaching physician to direct the care furnished by the resident, and to review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology.

Under § 415.180, we adopted a policy on an interim basis for the duration of the PHE for COVID–19 to allow PFS payment for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. A physician other than the resident must still review the resident's interpretation. Under § 415.184, we adopted a policy on an interim basis during the PHE for COVID–19 that the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met by the teaching physician's direct supervision using audio/video real-time communications technology. We considered whether the flexibilities described above that we implemented on an interim basis during the PHE for COVID–19 under §§ 415.172, 415.174, 415.180, and 415.184 should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether these policies should continue once the PHE for COVID–19 ends. We noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. In addition, we proposed to make a technical edit to the regulation text at § 415.184 to eliminate the term ''direct supervision'' to conform with the language in sections §§ 415.172, 415.174, and 415.180 regarding the presence of the teaching physician via audio/video real-time communications technology.

While we believe it was appropriate to permit teaching physicians to be involved in services furnished with residents through audio/video real-time communications technology to respond to critical needs during the PHE to reduce exposure risk and to increase the capacity of teaching settings to respond to COVID–19, we expressed concern that continuing to permit teaching physicians to be involved through their virtual presence may not be sufficient to warrant PFS payment to the teaching physician on a temporary or permanent basis. Absent the circumstances of the PHE for COVID–19, the physical, in-person presence of the teaching physician may be necessary to provide oversight to ensure that care furnished to Medicare beneficiaries is medically reasonable and necessary, and to ensure that the teaching physician renders sufficient personal services to exercise full, personal control of the key portion of the case.

We also noted concerns about patient safety when the teaching physician is only virtually present. For example, in the March 31st COVID–19 IFC, we excluded the surgical, high risk, interventional, endoscopic, or other complex procedures identified under § 415.172(a)(1), and anesthesia services under § 415.178 from the policy to allow the teaching physician to be present using audio-video real-time communications technology because we believed the requirement for the physical, in-person presence of the teaching physician for either the entire procedure or the key portion of the service with immediate availability throughout the procedure, as applicable, is necessary for patient safety given the risks associated with these services. In complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change. To permit payment under the PFS for these teaching physician services, we believed the services must be furnished with a certain level of personal oversight and involvement of the teaching physician who has the experience and judgment that is necessary for rapid on-site decision-making during these procedures.

We also noted that there may be circumstances in which virtual presence of the teaching physician, considered in light of the potential risks to patient safety and absent exposure risk concerns due to COVID–19, does not demonstrate sufficient personal involvement in the service to the patient to warrant payment to the teaching physician under the PFS. For example, a resident could evaluate a patient for change in mental status following surgery for hip fracture, perform a physical exam and report it as unrevealing, and note that the patient is uncooperative with a full exam. If a full exam had been performed by the

teaching physician or with the physical presence of the teaching physician (or with the teaching physician immediately available in the clinic to provide the necessary direction, under the primary care exception) to render personal and identifiable physicians' services to the patient, the exam would likely have revealed crystal-mediated acute arthritis, and that the patient's lack of cooperation was due to hypoactive delirium. However, the teaching physician may not have been able to identify this concern through the use of audio/video interactive communications technology. In this case, the presence of the teaching physician through audio/video interactive communications technology might have been insufficient to allow the teaching physician to render personal and identifiable physicians' services to exercise full, personal control over the key portion of the encounter.

We stated that there also may be certain patient populations that require greater clinical attentiveness and skill than the teaching physician could provide via audio/video interactive communications technology. For example, patients with cognitive impairment or dementia may require the experience and skill to recognize a need for specialized testing, and patients with communication disabilities may require more experience and skill to recognize specialized needs. It may not be possible for the teaching physician to meet these clinical needs and exercise full, personal control while being present for the key portion of the service through audio/video interactive communications technology. Moreover, the virtual connection between the teaching physician and the resident who is with the patient could be disrupted (as with any virtual supervision scenario), rendering it impossible for the teaching physician to provide necessary direction for the resident to furnish appropriate care to the patient, thus foreclosing the ability of the teaching physician to exercise full, personal control over the key portion of the services, and potentially putting the patient's safety at risk.

While we expressed significant concerns about extending our interim policy to permit virtual presence of the teaching physician, whether on a temporary or permanent basis, we noted that we believe public comments would be helpful as we further consider the status of this policy. For example, because COVID–19 may continue to persist in some communities after the expiration of the PHE for COVID–19, we considered extending our policy to permit the teaching physician to be present through audio/video interactive communications technology on a temporary basis until the end of the calendar year in which the PHE for COVID–19 ends. The presence of COVID–19 may result in a need for some teaching settings to continue to limit exposure risks, especially for high risk patients isolated for their own protection or in cases where the teaching physician has been exposed to the virus and must be under quarantine. If the teaching physician is under quarantine, termination of the policy to permit virtual presence of the teaching physician could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients in some communities, and could have the unintended consequence of limiting access to services for Medicare patients. Some communities may experience a resurgence of COVID–19, and extending our policy until the end of the calendar year in which the PHE for COVID–19 ends to permit PFS payment when the teaching physician is present through audio/video real-time communications technology could temporarily help teaching settings remain prepared with surge capacity.

Based on the clinical experience gained during the PHE for COVID–19, we noted that we might identify circumstances or procedures for which the teaching physician can routinely render sufficient personal and identifiable services to the patient to exercise full, personal control over the management of the key portion of the case when the services are furnished by a resident with the teaching physician present through audio/video real-time communications technology. For example, under ordinary circumstances for the primary care exception at § 415.174, we permit PFS payment to the teaching physician when a resident furnishes office/outpatient evaluation and management (E/M) visit codes of lower and mid-level complexity and annual wellness visits without the presence of a teaching physician (these codes are discussed in section II.F. of this final rule (85 FR XXXXX)). Additionally, the teaching physician may be able to provide sufficient involvement for simple procedures such as CPT code 36410 (*Venipuncture, age 3 years or older, necessitating the skill of a physician or other qualified health care professional (separate procedure), for diagnostic or therapeutic purposes (not to be used for routine venipuncture*) or CPT code 51701 (*Insertion of non-indwelling bladder catheter (e.g., straight catheterization for residual urine)*). For such circumstances and procedures, we stated that it may be appropriate to continue the virtual presence policy on a temporary or permanent basis.

We noted that having the virtual presence policy in place temporarily or permanently would not preclude teaching physicians from providing a greater degree of involvement in services furnished with residents, and teaching physicians would still have discretion to determine whether, and if so, when it is appropriate to be present virtually rather than in person depending on the services being furnished and the experience of the particular residents involved. We solicited comments to help us understand how the option to provide for teaching physician presence using audio/video real-time communications technology would support patient safety for all patients and particularly for at-risk patients (for example, patients who are aged and/or who have a disability); ensure burden reduction without creating risks to patient care or increasing fraud; avoid duplicative payment between the PFS and the IPPS for GME programs; and support emergency preparedness. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We received public comments on our proposal to make a technical edit to the regulation text at § 415.184 to eliminate the term ''direct supervision'' to conform with the language in sections §§ 415.172, 415.174, and 415.180 regarding the presence of the teaching physician via audio/video real-time communications technology. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters supported striking the term ''direct supervision'' from § 415.184 to conform to related sections describing the requirements for supervision of residents in teaching settings.

Response: We appreciate the commenters' support and are finalizing the technical edit to the regulation text at § 415.184 as proposed.

We also received public comments in response to the CY 2021 PFS proposed rule on whether the policies we adopted on an interim basis during the PHE for COVID–19 under §§ 415.172, 415.174, 415.180, and 415.184 should continue once the PHE ends. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the virtual presence policies in §§ 415.172,

415.174, 415.180, and 415.184 that we implemented on an interim basis during the PHE for COVID–19. Several commenters supported extending the flexibilities permanently and asserted that a permanent expansion would promote patient access to physicians' services, particularly in rural areas, as well as continuity, convenience, flexibility, choice, and a decrease in the spread of COVID–19. Another commenter stated that in rural settings, it was not always possible for the teaching physician to accompany a resident while also being present with other residents. This commenter stated that the ability for the resident to be physically with a patient while the teaching physician is virtually present has increased patient access to physicians' services in rural areas. Similarly, other commenters stated that the permanent ability for teaching physicians to be virtually present when not physically present could open up additional training opportunities to care for underserved populations or increase specialty training opportunities for rural training programs.

Commenters broadly supported the exclusion of surgical, high risk, interventional, endoscopic, or other complex procedures, including anesthesia, from the virtual presence policy. While supportive of the flexibilities that we implemented on an interim basis, some commenters recommended temporarily extending the policies through the end of the PHE for COVID–19 to provide flexibility for communities that may experience resurgences in COVID–19 infections. These commenters cited a need to gather data regarding patient safety and potential impacts on resident training outside the context of the PHE before considering permanent implementation of the policies. For example, one commenter noted that CMS could use data from procedures furnished by residents during the PHE under virtual presence of the teaching physician to determine which procedures may be appropriate for virtual supervision on an ongoing basis.

Response: We appreciate commenters' support of the virtual presence policies that we implemented on an interim basis during the PHE for COVID–19. We remain concerned that, absent the circumstances of the PHE, virtual presence may not allow the teaching physician to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act in most settings. For rural areas, however, we found compelling the commenters' statements that our virtual presence policy has increased access to Medicare-covered services. Accordingly, we believe that permitting the teaching physician to meet the requirements to bill under the PFS for their services through virtual presence when furnishing services involving residents in rural training settings could increase access to Medicare-covered services by preventing the beneficiary from potentially having to travel long distances to obtain care, particularly as rural areas have stretched and diminishing clinical workforces.[10]

Increasing beneficiary access to care in rural areas is also consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas.[11] Further, permitting the virtual presence of the teaching physician could facilitate expanded training opportunities for residents in rural settings, which have historically been in limited supply.[12] As such, the need to improve rural access to care for patients and training for residents overshadows our concerns about the ability for the teaching physician to render sufficient personal and identifiable physicians' services through virtual presence. Accordingly, we believe it would be appropriate to continue our policy to permit teaching physicians to meet the requirements to bill under the PFS for their services through virtual presence when furnishing services involving residents in rural settings after the conclusion of the PHE for COVID–19. This policy not only furthers our goals to increase beneficiary access to Medicare-covered services, it also facilitates needed training opportunities in a similar way to the longstanding primary care exception under § 415.174. The primary care exception permits the teaching physician to bill for certain types of physicians' services furnished by residents in certain settings even when the teaching physician is not present with the resident. Like the policy we are finalizing in this rule, the primary care exception facilitates access to Medicare-covered services and expanded residency training opportunities in primary care settings.

Therefore, we are finalizing a permanent policy to permit teaching physicians to meet the requirements to bill for their services involving residents through virtual presence, but only for services furnished in residency training sites that are located outside of an OMB-defined metropolitan statistical area (MSA).[13] In order to ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought in accordance with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying our existing documentation requirements to specify that, when a teaching physician, through virtual presence, furnishes services involving residents in a residency training site located outside of a MSA, the patient's medical record must clearly reflect how and when the teaching physician was present for the service in accordance with our regulations. For example, in the medical record, the teaching physician could document their physical or virtual presence at the training site during the key portion of a service, along with a notation describing the specific portion(s) of the service for which the teaching physician was virtually present, and/or that the teaching physician reviewed the service with the resident during or immediately after the service in accordance with the primary care exception under § 415.174. We also expect that, if the teaching physician is virtually present and bills for services during which there is a disruption to the virtual connection between the teaching physician and the resident who is with the patient, the encounter would be paused until the connection resumes, or the appointment would be rescheduled.

For all other settings, we are not permanently finalizing our teaching physician virtual presence policies; however, they will remain in place for the duration of the PHE to provide flexibility for communities that may experience resurgences in COVID–19 infections. While we do not anticipate any program integrity concerns to arise from this expanded flexibility in rural areas, we agree with commenters that it is necessary for use to consider

[10] Supply and Distribution of the Primary Care Workforce in Rural America: 2019: *https://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2020/06/RHRC_PB167_Larson.pdf. https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/reports/HRSA-Rural-Collaboration-Guide.pdf.*

[11] CMS Rural Health Strategy: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

[12] HHS awards $20 million to 27 organizations to increase the rural workforce through the creation of new rural residency programs: *https://www.hhs.gov/about/news/2019/07/18/hhs-awards-20-million-to-27-organizations-to-increase-rural-workforce.html.*

[13] Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.*

additional data prior to proposing additional policies in this area, which could range from expanding this flexibility to include non-rural settings to terminating this flexibility in all settings. Specifically, we anticipate considering to what degree the permanent establishment of the policy to permit teaching physician virtual presence in residency training sites that are located outside of a MSA increased patient access to Medicare-covered services and provided additional training opportunities for residents while enabling the teaching physician to render sufficient personal and identifiable physicians' services. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data or another assessment mechanism, to further study the impacts of this limited permanent expansion of the virtual presence policy to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

We are amending our regulations to reflect this final policy. In § 415.172(a), to conform with the regulation text we are finalizing to describe direct supervision in § 410.32(b)(3)(ii), we are adding language to state that, as a general rule, the required presence of a teaching physician in order to bill under the PFS for their services at a residency training site that is located outside of a MSA can be met through interactive, audio/video real-time communications technology, which, as noted above, means synchronous, interactive, audio and video communications technology, and does not include audio-only communications. We are also adding language to provide that, for the duration of the PHE for COVID–19, in all teaching settings, the required presence of a teaching physician can be met through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.172(a)(2), we are adding language to note the exceptions under which virtual presence is permitted in the case of E/M services.

In § 415.172(b), which discusses existing documentation requirements, we are adding language to clarify that, for residency training sites that are located outside of a MSA, the medical record must clearly reflect whether the teaching physician was physically or virtually present at the training site during the key portion of the service. We are also adding language to clarify that, for all teaching settings and for the duration of the PHE for COVID–19, the patient's medical record must clearly reflect whether the teaching physician was physically or virtually present during the key portion of the service. Finally, we are adding language to clarify that the medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.174(c), we are adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.174(d), we are adding language to state that, for residency training sites that are located outside of a MSA, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.180(a), we are adding language to state that, for residency training sites that are located outside of an MSA, PFS payment may be made for the interpretation of diagnostic radiology and other diagnostic tests when the interpretation is performed by a resident and when the teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only). We are also adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, PFS payment may be made for the interpretation of diagnostic radiology and other diagnostic tests when the interpretation is performed by a resident and when the teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only). Finally, we are adding language to clarify that the medical records must document the extent of the teaching physician's participation in the interpretation or review of the diagnostic radiology or diagnostic test.

In § 415.184, we are adding language to state that, for residency training sites that are located outside of a MSA, the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met using interactive, audio/video real-time communications technology (excluding audio-only). We are also adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met using interactive, audio/video real-time communications technology (excluding audio-only). Finally, we are adding language to clarify that the medical records must document the extent of the teaching physician's participation in the service.

While difficult to quantify, we believe that permanently extending the policy to permit virtual presence of teaching physicians in residency training sites that are located outside of an MSA will improve patient access to Medicare-covered physicians' services in rural areas. In addition, the ability of a teaching physician to meet the requirements to bill for services furnished involving residents through their virtual presence in these settings will improve teaching capabilities and potentially allow for additional resident education opportunities in rural areas. Settings that have traditionally been inaccessible as training sites for residents due to the limited ability of teaching physicians to be physically present will be more readily available, thereby affording increased access to physicians' services to patients in these areas. However, in order to ensure that this limited extension of the virtual presence policy is also consistent with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying our existing documentation requirements to specify that the medical record must clearly reflect how and when the teaching physician was present for the service. We believe this documentation clarification will ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought. Further, in order to minimize potential risks to patients, we remind physicians and other practitioners that the adoption of these virtual presence policies in residency training sites that are located outside a MSA does not preclude teaching physicians from being physically present when providing services furnished with residents. We therefore urge teaching physicians to continue to use their professional judgment to determine the circumstances under which it is appropriate to be present virtually rather than in person depending on the services being furnished and the experience of the

particular resident(s) and/or teaching physician involved.

Comment: In response to our comment solicitation for information regarding how the virtual presence of a teaching physician would support patient safety, several commenters stated that guardrails exist through the Accreditation Council for Graduate Medical Education (ACGME) and other accrediting organizations that have standards and systems to ensure patient safety and oversight of residents when virtual supervision of residents occurs.

Response: We appreciate commenters' suggestions that the policies of the ACGME and other accrediting organizations could serve as guardrails in the context of virtual supervision; however, the commenters provided no specific description of any such policies or any other evidence to further identify those guardrails. Without further information, CMS cannot opine on the sufficiency of ACGME or other accrediting organization policies. Therefore, we continue to rely on the clinical judgment of teaching physicians and the residents they involve in their care to ensure appropriate patient safety.

iii. Virtual Teaching Physician Presence During Medicare Telehealth Services

In the March 31st COVID–19 IFC (85 FR 19230), we adopted a policy on an interim basis to allow Medicare to make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology. We also noted that we were considering whether this policy should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, this policy could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether this policy should continue once the PHE for COVID–19 ends. We noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. Outside the circumstances of the PHE for COVID–19, under the requirements at section 1834(m) of the Act that discuss payment for telehealth services, the patient would be located at a telehealth originating site, and the teaching physician would be furnishing the service as the distant site practitioner with the involvement of the resident.

While teaching physician presence through audio/video real-time communications technology when a resident furnishes Medicare telehealth services was responsive to critical needs during the PHE for COVID–19 to reduce exposure risk and to increase the capacity of teaching settings to respond to COVID–19, we expressed concern that the policy to permit virtual presence of the teaching physician may not allow for sufficient personal and identifiable physicians' services to exercise full, personal control over the services such that PFS payment to the teaching physician would be appropriate outside the circumstances of the PHE for COVID–19 on a temporary or permanent basis. We also noted concern that if the resident was furnishing the service at the distant site and the teaching physician was at a third site and present with the resident through audio/video real-time communications technology, the teaching physician may not be able to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the service to warrant separate payment on the PFS.

Absent the need to reduce exposure risk to COVID–19 during the PHE, we also expressed some concerns about patient safety when the teaching physician is present only virtually during a telehealth service furnished by a resident. For example, the virtual connection between the teaching physician and the resident who is with the patient could be disrupted (as with any virtual supervision scenario), rendering it impossible for the teaching physician to provide necessary direction for the resident to furnish appropriate care to the patient, thus foreclosing the ability of the teaching physician to exercise full, personal control over the key portion of the service, and potentially putting the patient's safety at risk.

However, because COVID–19 may continue to persist in some communities and some communities may experience a resurgence of COVID–19 after the expiration of the PHE for COVID–19, we solicited comments about whether it would be appropriate to extend this policy on a temporary basis until the end of the calendar year in which the PHE for COVID–19 ends. The presence of COVID–19 may result in a need to continue to limit exposure risks. In cases where the teaching physician has been exposed to the virus and is under quarantine, termination of the policy to permit virtual presence of the teaching physician could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients in some communities, and could have the unintended consequence of limiting access for Medicare patients. Finally, based on experience gained during the PHE for COVID–19, we noted that we might identify circumstances for which the teaching physician can routinely render sufficient personal and identifiable services to the patient to exercise full, personal control over the management of the key portion of the case while providing virtual presence during Medicare telehealth services furnished by a resident on a permanent basis. For example, under ordinary circumstances for the primary care exception at § 415.174, we permit PFS payment to the teaching physician when a resident furnishes office/outpatient E/M visit codes of lower and mid-level complexity and annual wellness visits without the presence of a teaching physician (these codes were discussed in section II.F. of the proposed rule (85 FR 50121)). For such services, we noted that it may be appropriate to continue the virtual presence policy on a temporary or permanent basis. We solicited comments to help us understand how the option to allow teaching physician presence using audio/video real-time communications technology could support patient safety for all patients and particularly for at-risk patients (for example, patients who are aged and/or who have a disability), ensure burden reduction without creating risks to patient care or increasing fraud, avoid duplicative payment between the PFS and the IPPS for GME programs, and support emergency preparedness. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We received public comments on whether the policy we adopted on an interim final basis during the PHE for COVID–19 to allow Medicare to make payment under the PFS to the teaching physician when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology should continue once the PHE for COVID–19 ends. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of our interim policy to allow Medicare to make payment under the PFS to the teaching physician when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician

is present using audio/video real-time communications technology. Several commenters supported extending the flexibility permanently, while others recommended temporarily extending the policy through the end of the PHE for COVID–19, and cited a need to gather data regarding patient safety and potential impacts on resident training outside the context of the PHE for COVID–19. One commenter stated that in rural settings, it was not always possible for the teaching physician to accompany a resident while also being present to other residents. This commenter stated that the ability for the teaching physician is virtually present has increased patient access to physicians' services in rural areas. Similarly, other commenters stated that the permanent ability for teaching physicians to be virtually present when not physically present could increase training opportunities for rural training programs, and better prepare residents for the nuances and differences of providing care over video instead of in person.

Response: We appreciate commenters' support of our interim policy to allow Medicare to make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using interactive, audio/video real-time communications technology (excluding audio-only). We remain concerned that, absent the circumstances of the PHE, a teaching physician's presence via interactive, audio/video real-time communications technology (excluding audio-only) when a resident is furnishing Medicare telehealth services may not allow the teaching physician to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act, in most settings. For rural areas, however, we found compelling the commenters' statements that our virtual presence policy has increased access to Medicare-covered services. Accordingly, we believe that a policy to permit Medicare to make PFS payment for teaching physician services when a resident located within a rural training setting furnishes Medicare telehealth services to beneficiaries while a teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only) could increase access to Medicare-covered services in rural areas by preventing the beneficiary from potentially having to travel long distances to obtain care, particularly as rural areas have stretched and diminishing clinical workforces.[14] Increasing beneficiary access to care in rural areas is also consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas; therefore, in order to allow for more widespread access to care for beneficiaries in rural areas, we believe it would be appropriate for a resident located within a rural training setting to furnish telehealth services to a beneficiary who is in a separate location within the same rural area as the resident or within a different rural area, while a teaching physician is present, through interactive, audio/video real-time communications technology (excluding audio-only), in a third location, either within the same rural training setting as the resident or outside of that rural training setting.[15] Further, allowing Medicare to make PFS payment for teaching services when a resident furnishes Medicare telehealth services to a beneficiary while a teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only) could facilitate additional training opportunities for residents in rural settings, which have historically been in limited supply.[16] As such, the need to improve rural access to care for patients and training for residents overshadows our concerns about the ability for the teaching physician to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. Accordingly, in rural areas, we believe it would be appropriate to continue our policy to permit teaching physicians to meet the requirements to bill under the PFS for their services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only) after the conclusion of the PHE for COVID–19. This policy not only furthers our goals to increase beneficiary access to Medicare-covered services, it also facilitates needed training opportunities in a similar way to the longstanding primary care exception under § 415.174. The primary care exception permits the teaching physician to bill for certain types of physicians' services furnished by residents in certain settings even when the teaching physician is not present with the resident. Like the policy we are finalizing in this rule, the primary care exception facilitates access to Medicare-covered services and expanded residency training opportunities in primary care settings. Therefore, we are permanently finalizing our policy that Medicare may make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of a MSA to a beneficiary who is in a separate location outside the same MSA (that is, in the same rural area) as the residency training site or is within a rural area outside of a different MSA, while a teaching physician is present, through interactive, audio/video real-time communications technology (excluding audio-only), in a third location, either within the same rural training site as the resident or outside of that rural training site. In order to ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying our existing documentation requirements to specify that, when a resident furnishes Medicare telehealth services in a residency training site located outside of a MSA and the teaching physician is present using interactive, audio/video real-time communications technology (excluding audio-only), the patient's medical record must clearly reflect how and when the teaching physician was present during the key portion of the service, in accordance with our regulations. For example, in the medical record, the teaching physician could document their physical or virtual presence at the training site during the key portion of the service, along with a notation describing the specific portion(s) of the service for which the teaching physician was virtually present, and/or that the teaching physician reviewed the service with the resident during or immediately after the service in accordance with the primary

[14] A Guide for Rural Health Care Collaboration and Coordination: *https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/reports/HRSA-Rural-Collaboration-Guide.pdf.*

[15] CMS Rural Health Strategy: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

[16] HHS awards $20 million to 27 organizations to increase the rural workforce through the creation of new rural residency programs: *https://www.hhs.gov/about/news/2019/07/18/hhs-awards-20-million-to-27-organizations-to-increase-rural-workforce.html.*

care exception under § 415.174. We also expect that, if the teaching physician is virtually present and bills for services during which there is a disruption to the virtual connection between the teaching physician and the resident who is with the patient, the encounter would be paused until the connection resumes, or the appointment would be rescheduled.

For all other settings, we are not permanently finalizing this policy; however, the policy will remain in place for the duration of the PHE for COVID–19 to provide flexibility for communities that may experience resurgences in COVID–19 infections. While we do not anticipate any program integrity concerns from this expanded flexibility, we agree with commenters that it is necessary for us to consider additional data prior to proposing additional policies in this area, which could range from expanding this flexibility to include non-rural settings to terminating this flexibility in all settings. Specifically, we anticipate considering to what degree the permanent implementation of the policy to allow PFS payment for teaching services when a teaching physician is virtually present while a resident furnishes Medicare telehealth services in a residency training site located outside of an MSA increased patient access to Medicare-covered services and provided more training opportunities for residents while enabling the teaching physician to render sufficient personal and identifiable physicians' services. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data or another assessment mechanism, to further study the impacts of this limited permanent expansion of the policy to allow PFS payment for teaching services when a teaching physician is virtually present while a resident furnishes Medicare telehealth services to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

We are amending our regulations to reflect this final policy. In § 415.172(a), we are adding language to state that, in a residency training site located outside of an MSA, a teaching physician may bill under the PFS for services furnished when they are present with the resident during the key portion of the service through interactive, audio/video real-time communications technology (excluding audio-only), including when the resident provides Medicare telehealth services. We are also adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, payment under the PFS is permitted if a teaching physician is present during the key portion of the service, including Medicare telehealth services, through interactive, audio/video real-time communications technology (excluding audio-only). In § 415.172(b), which discusses existing documentation requirements, we are adding language to clarify that, for residency training sites that are located outside of a MSA, the patient's medical record must clearly reflect whether the teaching physician was physically or virtually present at the training site during the key portion of the service, including for Medicare telehealth services. We are also adding language to clarify that, for all teaching settings and for the duration of the PHE for COVID–19, the patient's medical record must clearly reflect whether the teaching physician was physically or virtually present during the key portion of the service, including for Medicare telehealth services. Finally, we are adding language to clarify that the medical records must contain a notation describing the specific portion(s) of the service, including Medicare telehealth services, for which the teaching physician was present through interactive, audio/video real-time communications technology (excluding audio-only).

While difficult to quantify, we believe that permanently extending our policy to allow payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of an MSA and the teaching physician is present through interactive audio/video real-time communications technology (excluding audio-only) will promote enhanced patient access to Medicare-covered physicians' services in rural areas. In addition, allowing PFS payment for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of an MSA and the teaching physician is present through interactive audio/video real-time communications technology (excluding audio-only) will improve teaching capabilities and potentially allow for additional resident education opportunities in rural areas. Settings that have traditionally been inaccessible as training sites for residents due to the limited ability of teaching physicians to be physically present will be more readily available, thereby affording increased access to physicians' services to patients in these areas. However, in order to ensure that the limited extension of this policy is also consistent with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying the existint documentation requirements to specify that the medical record must clearly reflect how and when the teaching physician was present for the Medicare telehealth service. We believe this documentation clarification will ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. Further, in order to minimize potential risks to patients, we remind physicians and other practitioners that the adoption of this policy in residency training sites that are located outside of an MSA does not preclude teaching physicians from being physically present when a resident is furnishing Medicare telehealth services. We therefore urge teaching physicians to continue to use their professional judgment to determine the circumstances under which it is appropriate to be present virtually rather than in person, depending on the Medicare telehealth services being furnished and the experience of the particular residents involved.

Comment: One commenter, who favored a permanent policy to allow PFS payment for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of a MSA and the teaching physician is present using interactive audio/video real-time communications technology, advocated for the permanent extension of the policy by noting that ACGME recognizes and endorses an expansion of telemedicine as well as the use of audio/visual communications devices by residents and their teaching physicians. Further, the commenter stated that, as long as the virtual presence of teaching physicians during Medicare telehealth services continues to adhere to ACGME standards, an optimal learning environment, with appropriate education and supervision, would be maintained.

Response: We appreciate the commenter's feedback regarding ACGME standards in the context of the expansion of telemedicine and the use of audio/visual communication devices by residents and teaching physicians; however, the commenter provided no specific description of ACGME's standards or any evidence to support a permanent implementation of the policy to allow PFS payment for teaching services when a resident furnishes Medicare telehealth services in all settings when a teaching physician is present through interactive, audio/video

real-time communications technology (excluding audio-only). Without further information, CMS cannot opine on whether or not ACGME's standards would support a wider permanent implementation of this policy. Therefore, we continue to rely on the clinical judgment of teaching physicians and the residents they involve in their care to ensure appropriate patient safety.

iv. Resident Moonlighting in the Inpatient Setting

Under certain conditions, the services of a licensed resident physician who is ''moonlighting'' are considered to be furnished by the individual in their capacity as a physician, rather than as a resident in an approved GME program. As specified in the regulation at § 415.208, except during the PHE for COVID–19, as defined in the regulation at § 400.200, the services of residents to inpatients of hospitals in which the residents have their approved GME program are not considered separately billable as physicians' services and instead are payable under §§ 413.75 through 413.83 regarding direct GME payments, whether or not the services are related to the approved GME training program. When a resident furnishes services that are not related to their approved GME programs in an outpatient department or emergency department of a hospital in which they have their training program, those services can be billed separately as physicians' services and payable under the PFS if they meet the criteria described in our regulation at § 415.208(b)(2)(i) through (iii). In addition, under § 415.208(c), services of a licensed resident furnished outside the scope of an approved GME program when moonlighting in a hospital or other setting that does not participate in the approved GME program are payable under the PFS when the resident is fully licensed to practice in the state where the services are furnished, and the resident's time spent in patient care activities in that setting is not counted for the purpose of Medicare direct GME payments.

In the March 31st COVID–19 IFC, we amended our regulation at § 415.208 to state that, during the PHE for COVID–19, the services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions for payment of physicians' services to beneficiaries by providers in § 415.102(a), the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the state in which the services are performed, and the services can be separately identified from those services that are required as part of the approved GME program. We considered whether this flexibility that we implemented on an interim basis should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether this policy should continue once the PHE ends. We expressed concerns that there may be risks to program integrity in allowing residents to furnish separately billable physicians' services to inpatients in the teaching hospitals where they are training when the services are outside the scope of their approved GME program. For example, there could be a risk of duplicate Medicare payment for the resident's services under the IPPS for GME and the PFS if the physicians' services furnished by residents were not adequately separately identified from those services that are required as part of the GME program. However, because COVID–19 may continue to persist in some communities or some communities may experience a resurgence of COVID–19 after the expiration of the PHE, we noted that it may be appropriate for us to extend this policy on a temporary basis to meet the needs of teaching hospitals to ensure that there are as many qualified practitioners available as possible. We noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in this CY 2021 PFS final rule. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We received public comments from our comment solicitation in the proposed rule regarding whether our resident moonlighting policy under § 415.208 that we implemented on an interim basis for the PHE for COVID–19 should continue once the PHE ends. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the policy under § 415.208 that we adopted on an interim basis during the PHE for COVID–19. Several commenters supported extending the flexibility permanently, while others recommended temporarily extending the policy through the end of the PHE for COVID–19, and cited a need to maintain surge capacity and to allow more data to be gathered regarding patient safety and potential impacts on resident training outside the context of the PHE. A few commenters suggested that to prevent duplicate billing, CMS should educate practitioners about the need for sufficient documentation to demonstrate that services furnished while residents are moonlighting are separate from those services that are required as part of approved GME programs.

Response: We appreciate commenters' support for our interim policy. After considering the comments, we are finalizing our interim policy for the services of moonlighting residents on a permanent basis. Consequently, we are amending our regulation at § 415.208(b)(2) to state that the services of residents that are not related to their approved GME programs and are performed in the outpatient department, emergency department, or inpatient setting of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions of payment for physicians' services to beneficiaries in providers in § 415.102(a), the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and the services are not performed as part of the approved GME program.

We agree with commenters about the need for sufficient documentation to allay concerns about potential duplication of payment with the IPPS for GME. Thus, we are also amending § 415.208(b)(2) to clarify that, regardless of whether the resident's services are performed in the outpatient department, emergency department or inpatient setting of a hospital in which they have their training program, the patient's medical record must clearly reflect that the resident furnished identifiable physician services that meet the conditions of payment of physician services to beneficiaries in providers in § 415.102(a), that the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and that the services are not performed as part of the approved GME program. For example, in the medical record, the resident could state that they are licensed to practice medicine, osteopathy, dentistry or podiatry by the

state in which the service was performed, document that the service was performed outside of their approved GME program, and include a notation describing the specific physician service that was furnished,

v. Primary Care Exception Policies

The regulation at § 415.174 sets forth an exception to the conditions for PFS payment for services furnished in teaching settings in the case of certain E/M services furnished in certain centers. Under the so-called ''primary care exception,'' Medicare makes PFS payment in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. Section 415.174(a)(3) requires that the teaching physician must not direct the care of more than four residents at a time, and must direct the care from such proximity as to constitute immediate availability (that is, provide direct supervision) and must review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. Section 415.174(a)(3) also requires that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, and ensure that the services furnished are appropriate.

As provided in the regulation at § 415.174(a), the codes of lower and mid-level complexity that can be furnished under the primary care exception are specified in section 100 of chapter 12 of the Medicare Claims Processing Manual (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*). They are the following:

- CPT code 99201 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99202 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services*);
- CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family*);
- HCPCS code G0402 (*Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment*);
- HCPCS code G0438 (*Annual wellness visit; includes a personalized prevention plan of service (PPS), initial visit*); and
- HCPCS code G0439 (*Annual wellness visit, includes a personalized prevention plan of service (PPS), subsequent visit*).

In the March 31st COVID–19 IFC, we amended § 415.174 of our regulations to allow, during the PHE for COVID–19, all levels of office/outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. In the May 8th COVID–19 IFC), we further expanded the list of services included in the primary care exception during the PHE for COVID–19. We also allowed PFS payment to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services.

We noted that we were considering whether these policies should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether these policies should continue once the PHE for COVID–19 ends. We also noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. We also considered whether specific services added under the primary care exception should be extended temporarily or made permanent and solicited public comments on whether these services should continue as part of the primary care exception once the PHE for COVID–19 ends. These services are the following:

- CPT code 99204 *(Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or*

coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family);

- CPT code 99205 *(Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family);*
- CPT code 99214 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family);*
- CPT code 99215 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family);*
- CPT code 99495 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*);
- CPT code 99496 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*);
- CPT code 99421 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*);
- CPT code 99422 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*);
- CPT code 99423 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*);
- CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes*);
- HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*); and
- HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*).

We noted that expanding the array of services for which Medicare may make PFS payment to the teaching physician when furnished by a resident under the primary care exception was responsive to critical needs during the PHE for COVID–19 for patients who may be quarantined at home or who may need to be isolated for purposes of minimizing exposure risk based on presumed or confirmed COVID–19 infection. Because COVID–19 may continue to persist in some communities or some communities may experience a resurgence of COVID–19 after the expiration of the PHE for COVID–19, we also noted that it may be appropriate for us to extend all of these services on a temporary basis (that is, until the end of the calendar year in which the PHE for COVID–19 ends).

However, we expressed concern that it may be inappropriate to extend all of these services on a temporary basis or add them to the primary care exception permanently. The intent of the primary care exception as described in § 415.174 is that E/M visits of lower and mid-level complexity furnished by residents are simple enough to permit a teaching physician to be able to direct and manage the care of up to four residents at any given time and direct the care from such proximity as to constitute immediate availability. While CPT code 99421 and HCPCS code G2012 may be simple services, others such as levels 4 and 5 office/outpatient E/M visits (CPT codes 99204 through 99205 and CPT codes 99214 through 99215) and transitional care management codes (CPT codes 99495 through 99496) require medical decision-making that is of at least moderate complexity. We also noted concern that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. We noted that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision-making, the ability to be immediately available to other residents could be compromised, potentially putting patients at risk. Thus, we considered whether, upon expiration of the PHE for COVID–19, we should extend on a temporary basis some or all of the services we added to the primary care exception list during the PHE and solicited public comments on whether these services should continue as part of the primary care exception after the PHE ends. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We also considered whether our interim policy that PFS payment could be made to the teaching physician when residents furnish telehealth services under the primary care exception should be extended on a temporary basis or be made permanent, and solicited public comments on whether this policy should continue once the

PHE for COVID–19 ends. In these cases, outside the circumstances of the PHE for COVID–19, the patient would be at the originating site and the resident furnishing the care, along with the teaching physician billing for it, would be located at the primary care center as the distant site practitioner. If we were to temporarily extend or add permanently to the primary care exception services such as e-visits or communication technology-based services, we noted that it may also make sense to permit PFS payment to the teaching physician when the resident furnishes an office/outpatient E/M visit via telehealth, on the basis that the patient is not physically in the clinic and that these services all involve the use of virtual technology (for example, patient portals for e-visits, telecommunications technology for the office/outpatient E/M visit) to facilitate care delivery. Further, we noted that, if we were to remove the services that we added to the primary care exception on an interim basis, we could separately consider continuing to permit PFS payment to the teaching physician when the resident furnishes an office/outpatient E/M visit via telehealth because the teaching physician would be immediately available in the distant site clinic with the resident to direct and manage the care.

We received public comments on the primary care exception policies. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the policy adopted on an interim basis under § 415.174 to allow Medicare to make payment to the teaching physician for additional services under the primary care exception, including all levels of office and outpatient E/M, audio-only telephone E/M services, transitional care management, and communication technology-based services. Commenters were also generally supportive of our interim policy to allow Medicare to make payment under the PFS to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services are on the list of Medicare telehealth services. These commenters stated that in general, the expansion of the primary care exception increases beneficiary access to Medicare-covered services and provides additional training opportunities for residents, particularly in rural areas.

Several commenters supported making permanent all the services that we implemented on an interim basis during the PHE for COVID–19. Several other commenters supported making certain services permanent, stating that services such as communication technology-based services (for example, CPT codes 99421–99423 and HCPCS codes G2010 and G2012) were simple, require low to moderate complexity medical decision-making, and do not involve a diagnostic complexity that is beyond a resident's skill. In addition, some commenters supported the permanent inclusion of CPT code 99452 and stated that in some models of care, these inter-professional consults are typically initiated by a primary care practitioner to a specialist for a low acuity, condition-specific question that can be answered without an in-person visit.

Some commenters supported the permanent inclusion of CPT codes 99204 and 99214, while other commenters did not. Commenters in support of including these codes stated that office/outpatient level 4 visits are typical visit for the Medicare population and that these visits do not involve a level of diagnostic complexity that is beyond a resident's skill. Other commenters stated that office/outpatient level 4 visits should be furnished with the teaching physician present, either physically or through interactive audio/video real-time communications technology. These commenters were concerned that allowing office/outpatient level 4 visits to be furnished without the presence of the teaching physician could pose risks to patient safety and potential for abuse.

Some commenters did not support the permanent inclusion of high-complexity services, including office/outpatient level 5 visits (CPT codes 99205 and 99215) and transitional care management (CPT code 99496), due to the high level of medical complexity, patient safety concerns, and potential for abuse.

Several commenters recommended temporarily extending the primary care exception policies through the end of the PHE for COVID–19 and cited a need to gather data regarding patient safety and potential impacts on resident training outside the context of the PHE. Other commenters stated that the expansion of the primary care exception has allowed residents to be trained based on ''real life,'' which will leave them better prepared to furnish additional services upon completion of their residency programs.

Response: We appreciate commenters' support of our interim policy to allow Medicare to make payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception. We remain concerned that permanently adding all of the proposed services to the primary care exception may be inappropriate because some of the services require at least a moderate level of medical decision-making, whereas the intent of the primary care exception as described in § 415.174 is that E/M visits of lower and mid-level complexity furnished by residents are simple enough for a teaching physician to be able to direct and manage the care of up to four residents at any given time and direct the care from such proximity as to constitute immediate availability. We also remain concerned that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. However, we found the comments regarding the advantages of an expansion of services under the primary care exception in rural areas particularly compelling. Specifically, allowing PFS payment for additional primary care services furnished by residents without the physical presence of a teaching physician in rural areas could increase the availability of Medicare-covered services, which is consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas[17]. For example, permitting PFS payment to the teaching physician when the resident furnishes communication-technology based services, an inter-professional consultation, or an office/outpatient visit via telehealth without a teaching physician present could prevent the beneficiary from potentially having to travel long distances to obtain care. Accordingly, we believe that permitting Medicare to make PFS payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception in rural settings could increase access to Medicare-covered services. Further, this policy could also provide the benefit of additional training opportunities for residents in rural settings, which have historically been in limited supply. As such, the need to improve rural access to care for patients and training for resident overshadows our concerns that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when

[17] CMS Rural Health Strategy: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

some or all of the residents might be furnishing services that are more than lower and mid-level complexity. Accordingly, we are finalizing, for residency training sites that are located outside of a MSA, a policy to allow Medicare to make payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception. However, in accordance with the original intent of the primary care exception to limit the scope of services to those of lower and mid-level complexity, we are limiting the permanent expanded array of services under the primary care exception to include communication-technology based services and inter-professional consults. These services are described by CPT codes 99421–99423, and 99452, and HCPCS codes G2010 and G2012. We are also adding to the primary care exception, for residency training sites that are located outside of an MSA, Medicare telehealth services that furnished by residents. Based on the descriptors, these codes all represent E/M services of a low-to-mid-level complexity, which is consistent with our regulations in § 415.174.

As noted above, some commenters supported adding office/outpatient E/M level 4 visits (CPT codes 99204 and 99214) to the primary care exception. While we included these services in the exception during the PHE to meet the needs of all teaching settings to ensure that there are as many qualified practitioners available as possible, we agree with the commenters who stated that it is inappropriate to allow these services to be billed by the teaching physician when furnished by residents without the presence of a teaching physician on a permanent basis because these services involve medical decision-making of at least a moderate level of complexity, so the ability for the teaching physician to be immediately available to other residents could be compromised. Thus, we agree with the commenters who stated that adding office/outpatient E/M level 4 visits to the primary care exception could pose risks to patient safety. We also believe that, because the transitional care management codes require medical decision-making of at least moderate complexity, the ability for the teaching physician to be immediately available to other residents could be compromised.

This policy to limit the expanded array of services permitted to be furnished under the primary exception only to those services furnished in residency training sites that are located outside of a MSA is consistent with other teaching physician payment policies regarding virtual presence and telehealth that we are finalizing as described earlier in this final rule, and which were also similarly limited to residency training sites that are located outside of a MSA. However, practitioners are reminded that the permanent extension of the expanded primary care exception in residency training sites that are located outside of a MSA does not preclude teaching physicians from being physically present when a resident is furnishing these primary care services. We therefore urge teaching physicians to continue to use their professional judgment to determine the circumstances under which it is appropriate for residents to perform these services without the presence of the teaching physician, depending on the Medicare service being furnished and the experience of the particular resident involved.

For all other settings, we are not finalizing a policy to allow Medicare to make payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception, including when those services are furnished under Medicare telehealth; however, the interim policy to include an expanded set of services under the primary care exception will remain in place for the duration of the PHE for COVID–19 to provide flexibility for communities that may experience resurgences in COVID–19 infections. Accordingly, at the end of the PHE, we will be terminating the inclusion of CPT codes 99204, 99214, 99205, 99215, 99495 and 99496 from the primary care exception for all settings.

While we do not anticipate any program integrity concerns to arise from the final policy to expand the services that may be furnished under the primary care exception in rural settings, we also agree with commenters that it is necessary for us to consider additional data prior to proposing additional policies in this area, which could range from expanding this flexibility to include non-rural settings to terminating this flexibility in all settings. Specifically, anticipate considering to what degree the permanent establishment of the policy to allow PFS payment to teaching physicians when the resident furnishes an expanded array of services under the primary care exception in residency training sites that are located outside of an MSA increased patient access to care and provided more training opportunities for residents while enabling the teaching physician to remain immediately available. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data or another assessment mechanism, to further study the impacts of this limited permanent expansion of the policy to allow PFS payment to teaching physicians when the resident furnishes an expanded array of services under the primary care exception in residency training sites of a teaching setting that are outside of an MSA to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

Comment: One commenter requested clarification that when teaching physicians meet all of the requirements of the primary care exception, they are also able to provide direction and immediate availability thru virtual presence for moderate to high complexity encounters, such CPT codes 99204, 99205, 99214, and 99215.

Response: Through the end of the PHE for COVID–19, a teaching physician that meets the requirements of the primary care exception described in § 415.174(c) to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through interactive, audio/video real-time communications technology (excluding audio-only). This policy applies for moderate to high complexity encounters, including all levels of office/outpatient services. Once the PHE for COVID–19 ends, in accordance with the final policy to allow PFS payment to teaching physicians when the resident furnishes an expanded array of services under the primary care exception in residency training sites that are located outside of an MSA, a teaching physician may meet the requirements of the primary care exception described in § 415.174 to direct the care and then to review the services furnished by each resident during or immediately after each visit through interactive, audio/video real-time communications technology (excluding audio-only) when residents furnish services that we are including under the primary care exception, as described above. We believe that establishing this policy for residency training sites that are located outside of an MSA is consistent with the expansion of services that are permitted under the primary care exception in residency training sites that are located outside of an MSA, and that similarly, this policy will also increase beneficiary access to Medicare-covered primary care services and provide additional training opportunities for residents in settings to which there has previously been limited access. However, as noted above, the

services we are permanently including under the primary care exception in residency training sites that are located outside of an MSA do not include codes 99204, 99214, 99205, 99215, 99495 and 99496 because these services are of moderate to high complexity, and we believe it is inappropriate to allow these services to be furnished by residents without the presence of a teaching physician.

We are amending our regulations to reflect this final policy. In § 415.174, we are adding a new paragraph (d) to state that, in residency training sites that are located outside of an MSA, a teaching physician that meets the requirements of the primary care exception described in § 415.174 may meet the requirement to direct the care and then to review the services furnished by each resident during or immediately after each visit through interactive, audio/video real-time communications technology (excluding audio-only) when residents furnish services that are included under the primary care exception associated with these sites.

Comment: One commenter requested clarification that office/outpatient E/M services furnished by residents under the primary care exception described in § 415.174 may be billed on the basis of time, and also requested confirmation that, under the primary care exception, the teaching physician need not be present with the resident for the period of time billed.

Response: In the May 8th COVID–19 IFC, we stated that, consistent with policy that we established in the March 31st COVID–19 IFC for selecting the level of office/outpatient E/M visits when furnished as Medicare telehealth services, (85 FR 19268 through 19269), the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on medical decision-making or time, with time defined as all of the time associated with the E/M on the day of the encounter; and the requirements regarding documentation of history and/or physical exam in the medical record do not apply. As described in section II.Z. of the May 8th COVID–19 IFC, the typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor.

vi. Conclusion

In summary, we reminded stakeholders that during the PHE for COVID–19 we implemented these policies on an interim basis to support our goals of ensuring beneficiary access to necessary services and maintenance of sufficient workforce capacity by offering flexibility to practitioners. While we anticipated reverting to our previous teaching physician policy that was in place prior to the PHE for COVID–19 for the reasons discussed above, we considered whether the teaching physician and resident moonlighting policies that we implemented on an interim basis during the PHE for COVID–19 should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent policy for CY 2021. As discussed above, we noted concern that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower or mid-level complexity. We also noted concern that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision-making, their ability to be immediately available to other residents could be compromised, which can potentially put patients at risk. We noted that we would consider under which scenarios our policies for moonlighting or virtual presence as discussed above, should apply, if any. As discussed for our moonlighting policy, we expressed concern that there may be risks to program integrity in allowing residents to furnish separately billable physicians' services to inpatients in the teaching hospitals where they are training when the services are outside the scope of their approved GME program. For example, there could be a risk of duplicate Medicare payment for the resident's services under the IPPS for GME and the PFS if the physicians' services furnished by residents were not adequately separately identified from those services that are required as part of the GME program. Under our discussion of virtual presence, we highlighted concerns about how continuing to permit teaching physicians to be involved through their virtual presence may not be sufficient to warrant PFS payment to the teaching physician on a temporary or permanent basis. Absent the circumstances of the PHE for COVID–19, the physical, in-person presence of the teaching physician may be necessary to provide oversight to ensure that care furnished to Medicare beneficiaries is medically reasonable and necessary, and to ensure that the teaching physician renders sufficient personal services to exercise full, personal control of the key portion of the case. We also discussed concerns about patient safety when the teaching physician is only virtually present.

We noted that public comments, especially those that focused on the variables we identified regarding the specific services included on the primary care exception list, and clinical scenarios under which residents could moonlight or furnish certain types of services under the supervision of a teaching physician via virtual presence, would assist us in identifying the appropriate policy continuation decisions after the end of the PHE for COVID–19, which we would consider while drafting this CY 2021 PFS final rule. As part of our review of public comments, we would weigh and make decisions based on the potential benefits and risks associated with the potential temporary or permanent continuation, in whole or in part, of these policies. We noted that the benefits of continuation may include limiting COVID–19 exposure risk for practitioners and patients, increasing workforce capacity of teaching settings to respond to continuing effects following the PHE for COVID–19 as practitioners may be asked to assist with the response, and increasing access so that we do not unintentionally limit the number of licensed practitioners available to furnish services to Medicare beneficiaries. We noted that the risks may include the potential for duplicative payment with Medicare Part A reimbursement for GME training programs, the potential for increases to cost-sharing for Medicare beneficiaries that could result from additional Part B claims for services furnished by the teaching physician with the involvement of residents, and potential threats to patient safety.

Comment: Commenters were generally supportive of the teaching physician and resident moonlighting policies that we implemented on an interim basis during the PHE for COVID–19. Several commenters recommended that we finalize our policies and asserted that making these policies permanent would promote patient access to physicians' services, particularly in rural and underserved areas and could provide additional training opportunities for rural training programs. Other commenters recommended that we extend the policies on a temporary basis, to provide flexibility for communities that may experience resurgences in COVID–19 infections. In addition, these commenters cited a need to gather data regarding patient safety and potential

impacts on resident training outside the context of the PHE before considering permanent implementation of the polices.

Response: We appreciate commenters' support of the teaching physician and resident moonlighting policies that we implemented on an interim basis during the PHE for COVID–19. As we reviewed these comments, we considered the benefits and risks of finalizing the proposals. After considering the comments, we are finalizing our virtual presence and primary care exception policies for residency training sites that are located outside of an MSA. We are finalizing our resident moonlighting policies for all inpatient teaching settings.

We found compelling the comments regarding the benefits of the virtual presence and primary care exception policies in rural settings. Accordingly, we believe that permitting the teaching physician to meet the requirements to bill under the PFS for their services through virtual presence when furnishing services involving residents in rural training settings, and allowing PFS payment for additional primary care services furnished by residents without the physical presence of a teaching physician in rural areas could increase access to Medicare-covered services by preventing the beneficiary from potentially having to travel long distances to obtain care, particularly as rural areas have stretched and diminishing clinical workforces.[18] Increasing beneficiary access to care in rural areas is also consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas.[19] Further, these policies could provide the benefit of additional training opportunities for residents in rural settings, which have historically been in limited supply.[20] As such, the need to improve rural access to care for patients and training for residents overshadows our aforementioned concerns about the teaching physician's ability to render sufficient personal and identifiable physicians' services through virtual presence, or to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. Accordingly, we believe it would be appropriate to continue these policies in rural settings after the conclusion of the PHE for COVID–19. These policies not only further our goal to increase beneficiary access to Medicare-covered services, they also facilitate needed training opportunities is similar to the rationale for the existing primary care exception under § 415.174. The primary care exception permits the teaching physician to bill for certain types of physicians' services furnished by residents in certain settings even when the teaching physician is not present with the resident. Like the policies we are finalizing in this rule, the primary care exception facilitates access to Medicare-covered services and expanded residency training opportunities in primary care settings. Therefore, we are finalizing our virtual presence and primary care exception policies for residency training sites that are located outside of an OMB-defined MSA. In addition, in order to ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought in accordance with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying existing documentation requirements to specify that the patient's medical record must clearly reflect how and when the teaching physician was present during the key portion of the service, in accordance with our regulations.

For our resident moonlighting policies, we believe that complete documentation in the medical record would guard against the risk of potential duplicative payment with the IPPS. Consequently, we are clarifying that, regardless of whether the resident's services are performed in the outpatient department, emergency department or inpatient setting of a hospital in which they have their training program, the patient's medical record must clearly reflect that the resident furnished identifiable physician services that meet the conditions of payment of physician services to beneficiaries in providers in § 415.102(a), that the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and that the services are not performed as part of the approved GME program.

For the virtual presence, primary care exception and resident moonlighting policies, while we do not anticipate any program integrity concerns, we agree with commenters that it is necessary for us to consider additional data prior to proposing additional policies in this area, which could range from expanding these flexibilities to include non-rural settings to terminating these flexibilities in all settings. Specifically, we anticipate considering to what degree the permanent establishment of these policies increased patient access to Medicare-covered services and provided additional training opportunities for residents while enabling the teaching physician to render sufficient personal and identifiable physicians' services. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data, or another assessment mechanism, to further study the impacts of these policies to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

2. Supervision of Diagnostic Tests by Certain NPPs

In response to E.O. 13890 discussed above, we sought assistance from stakeholders in identifying Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. In response to our request for feedback discussed above, physician assistants (PAs) and nurse practitioners (NPs) recommended regulatory changes that would allow them to supervise the performance of diagnostic tests because they are currently authorized to do so under their state scope of practice rules in many states. In the May 8th COVID–19 IFC (85 FR 27550 through 27629), we established on an interim basis during the PHE for COVID–19, a policy to permit these and certain other NPPs to supervise diagnostic tests. In the CY 2021 PFS proposed rule, we proposed to make those changes permanent by making modifications to the regulations at § 410.32. We noted that we planned to address comments we received on the proposals from the CY 2021 PFS proposed rule and comments received on the May 8th COVID–19 IFC (85 FR 27550 through 27629) simultaneously in this final rule.

Prior to the PHE for COVID–19, under § 410.32(a)(2), physicians, NPs, CNSs, PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who are treating

[18] A Guide for Rural Health Care Collaboration and Coordination: *https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/reports/HRSA-Rural-Collaboration-Guide.pdf.*

[19] CMS Rural Health Strategy. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

[20] HHS awards $20 million to 27 organizations to increase the rural workforce through the creation of new rural residency programs: *https://www.hhs.gov/about/news/2019/07/18/hhs-awards-20-million-to-27-organizations-to-increase-rural-workforce.html.*

a beneficiary for a specific medical problem may order diagnostic tests when they use the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests. The regulation at § 410.32(b)(1) provided as a basic general rule that all diagnostic tests paid under the PFS must be furnished under an appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b)(2) then provided for certain exceptions to which this basic rule did not apply. For instance, under § 410.32(b)(2)(v), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by an NP or CNS authorized under applicable state law to furnish the test. (We noted that, as for all services furnished by a NP or CNS, they would have to be furnished working in collaboration with a physician as provided in regulations at §§ 410.75 and 410.76, respectively). Similarly, under the regulation at § 410.32(b)(2)(vii), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by a CNM authorized under applicable state law to furnish the test. This exception is in place because the Medicare statute does not include any physician supervision requirement for CNM services. Thus, while NPs, CNSs, PAs, and CNMs were permitted to furnish diagnostic tests to the extent they were authorized under state law and their scope of practice to do so, the regulations at § 410.32 did not address whether these practitioners could supervise others who furnished diagnostic tests.

In light of stakeholder feedback to CMS on identifying additional Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license, effective January 1, 2021, we proposed to amend the basic rule under the regulation at § 410.32(b)(1) to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice. These NPPs have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physician's services if furnished by a physician, and are authorized to receive payment under Medicare Part B for the professional services they furnish either directly or ''incident to'' their own professional services, to the extent authorized under state law and scope of practice.

We proposed to amend the regulation at § 410.32(b)(2)(iii)(B) on a permanent basis to specify that supervision of diagnostic psychological and neuropsychological testing services can be done by NPs, CNS's, PAs or CNMs to the extent that they are authorized to perform the tests under applicable State law and scope of practice, in addition to physicians and CPs who are currently authorized to supervise these tests. We also proposed to amend on a permanent basis, the regulation at § 410.32 to add paragraph (b)(2)(ix) to specify that diagnostic tests performed by a PA in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians as defined under § 410.74 would continue to apply. We also proposed to make permanent the removal of the parenthetical, previously made as part of the May 8th COVID–19 IFC (85 FR 27550 through 27629), at § 410.32(b)(3) that required a general level of physician supervision for diagnostic tests performed by a PA.

We received public comments on whether the policies we adopted on an interim basis during the PHE for COVID–19 under § 410.32 should continue once the PHE ends. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing appreciation for the flexibilities that we put in place for purposes of the PHE for COVID–19, allowing NPPs to supervise the performance of diagnostic tests and treat patients at the top of their scope of practice. Additionally, they encouraged CMS to make this flexibility permanent, beyond the COVID–19 pandemic.

Response: We appreciate the feedback from these commenters and plan to finalize these provisions as proposed, with modifications described below.

Comment: We received a comment that certified registered nurse anesthetists (CRNAs) should be listed among the delineated NPPs, explaining the value of their services within the health care system. The commenter noted that in the CY 2013 PFS final rule (77 FR 69006), CMS indicated Medicare coverage of CRNA services within their state scope of practice. The commenter stated that CRNAs have continuously practiced autonomously, and provide every aspect of anesthesia delivery as well as acute and chronic pain management services.

Response: We appreciate the information provided and are adding CRNAs to the previously enumerated list of NPPs.

Comment: Some commenters opposed our proposed change to allow NPPs to supervise the performance of psychological and neuropsychological tests. These commenters provided information indicating that these tests are not within the scope of practice of the proposed NPPs, and require special training only available to psychologists and physicians.

Response: We appreciate the information provided by these commenters stating that the specified NPPs are not qualified or authorized by their scope of practice and State law to supervise the performance of this specific category of diagnostic tests. As directed under the E.O. to allow NPPs to practice at the top of their license, our intent regarding this supervision flexibility is to allow NPPs with separate benefit categories under Medicare law to supervise the performance of diagnostic tests, regardless of the specific category of diagnostic tests, only to the extent their scope of practice and State laws authorize them to do so. Accordingly, we believe that the scope of practice and State laws for the State in which the specified NPPs furnish diagnostic psychological and neuropsychological tests will determine whether these NPPs are qualified to supervise the performance of diagnostic psychological and neuropsychological tests in addition to physicians and clinical psychologists who are already authorized to supervise such tests.

Comment: Some commenters expressed concern about the ability of NPPs to supervise diagnostic tests beyond the PHE for COVID–19. They opined that such supervision should not extend beyond the PHE for COVID–19. These commenters expressed that while NPPs are critical team members, it is vital to maintain physician-led teams for quality and cost of care. They cited information indicating that NPPs order more tests and prescribe opioids more than physicians, that patients prefer physicians, and that increasing the supply of NPPs does not increase access to care.

Response: We appreciate the commenters' feedback; however, we did not find sufficient evidence to support altering our proposal. Accordingly, we are finalizing our policy as proposed on a permanent basis and amending regulations text at § 410.32(b) to include CRNAs in the group of specified NPPs with a separately enumerated Medicare benefit category to who are allowed to supervise the performance of diagnostic tests, as permitted within their scope of

practice and State law for the State in which the test is furnished.

3. Pharmacists Providing Services Incident to Physicians' Services

Stakeholders have asked us to clarify that pharmacists can provide services incident to the professional services of a physician or other NPP just as other clinical staff may do. These stakeholders have asked us, in particular, about pharmacists who provide medication management services. Medication management is covered under both Medicare Part B and Part D. We are reiterating the clarification we provided in the May 8th COVID–19 IFC (85 FR 27550 through 27629), that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.

We noted that when a pharmacist provides services that are paid under the Part D benefit, the services are not also reportable or paid for under Part B. In addition to circumstances where medication management is offered as part of the Part D benefit, Part B payment is also not available for services included in the Medicare Part D dispensing fees, such as a pharmacist's time in checking the computer for information about an individual's coverage, measurement or mixing of the covered Part D drug, filling the container, physically providing or delivering the completed prescription to the Part D enrollee. Similarly, performing required quality assurance activities consistent with § 423.153(c)(2), such as screening for potential drug therapy problems due to therapeutic duplication, age/gender-related contraindications, potential over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse are considered part of dispensing fees under Part D and are not separately reportable services under Part B. Additionally, services and supplies paid under the incident to benefit must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness (§ 410.26). We also noted that our manual provisions specify that ''incident to'' services must be of a type that are medically appropriate to provide in the office setting; and that where a physician supervises auxiliary personnel to assist him or her in rendering services to patients and includes the charges for their services in his or her own bills, the services of such personnel are considered incident to the physicians' service if there is a physicians' service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician (section 60.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100–02) available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*).

Although it is fully consistent with current CMS policy for pharmacists to provide services incident to the services of the billing physician or NPP, we believe this clarification may encourage pharmacists to work with physicians and NPPs in new ways where pharmacists are working at the top of their training, licensure and scope of practice. It may free up the time of physicians and NPPs for other work and increase access to medication management services, for individuals with chronic conditions and other conditions. As an example, we found that this clarification was helpful in recently addressing in the May 8th COVID–19 IFC (85 FR 27550 through 27629), the ability of pharmacies to enroll as laboratories and work with physicians in the assessment of clinical information, specimen collection and reporting results of COVID–19 clinical diagnostic laboratory tests.

We received a few public comments on this clarification made in our IFC and proposed rule. The following is a summary of the comments we received and our responses.

Comment: We received several comments asking us to allow pharmacists to directly bill office/outpatient E/M visit codes (CPT codes 99202–99215), or if this is not possible, allow physicians to bill these codes for time spent by pharmacists providing services incident to a physician's service. One commenter questioned why we referred to pharmacists as auxiliary staff or auxiliary personnel, and whether the AMA CPT Editorial Panel would agree with this classification.

Response: As mentioned above, the Medicare Part B benefit category of services furnished ''incident to'' the professional services of a physician, describe services furnished by the staff (or contracted staff) of a physician under his or her supervision. Specifically, section 1861(s)(2)(A) of the Act describes, services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills.'' Our regulation that implements section 1861(s)(2)(A) of the Act similarly describes these services in § 410.26(b) where we specify, among other things, that ''incident to'' services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness. In the regulation at § 410.26(a), we have long used the term ''auxiliary personnel'' to describe the individuals who may provide services incident to the professional services of a physician or practitioner who is authorized by law to bill Medicare for their services. The regulation defines the term as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets other stated rules, including licensure rules imposed by the State in which the services are being furnished. This Medicare Part B framework applies to any individual working with the billing physician or other practitioner to provide services on an ''incident to'' basis, for example, a physician assistant, medical assistant, nurse, pharmacist, administrative assistant or others, whether they have a clinical role or not. The Medicare term ''auxiliary personnel'' could include staff that have clinical roles and staff that do not.

The CPT codebook that delineates a common system of codes for use by all payers, describes individuals who perform or report a given service using different terms, ''physician or qualified health care professional'' (QHP) and ''clinical staff.'' The CPT codebook defines these terms as follows, ''A 'physician or other qualified health care professional' as an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that

professional service. These professionals are distinct from 'clinical staff.' A clinical staff member is a person who works under the supervision of physician or other qualified healthcare professional, and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a professional service, but does not individually report that professional service. Other policies may also affect who may report specific services.'' [21] Under the PFS, we sometimes use the term ''clinical staff'' to describe specially qualified auxiliary personnel who perform services specifically comprised of ''clinical staff'' time (such as chronic care management services by clinical staff), even though our regulations refers to them as ''auxiliary personnel.'' Under the PFS, ''clinical staff'' is a subset of ''auxiliary personnel.''

As commenters noted, pharmacists could be considered QHPs by some other payers who provide for their direct payment. We do not consider them such because there is no Medicare statutory benefit allowing them to enroll, bill and receive direct payment for PFS services. As such, pharmacists are not among the physicians and QHPs that can furnish and bill for the 2021 office/outpatient E/M visit codes, because levels two through five are by definition only performed and directly reported by physicians or QHPs.[22] For example, when time is used to select visit level, only the time of the physician or QHP is counted. By definition, these codes cannot be furnished and billed as ''incident to'' services; therefore, they cannot be used to report services consisting of time spent solely by a pharmacist working ''incident to'' the services of a billing physician. We also note that services furnished directly by pharmacists are listed in a separate section of the CPT Codebook that includes codes describing Medication Therapy Management Services.[23]

In summary, we agree with certain stakeholders that under the general CPT framework, pharmacists could be considered QHPs or clinical staff, depending on their role in a given service. However, under the current Medicare law which includes the PFS, we do not have ability to pay (or even price) services that are furnished and billed directly by pharmacists. Regarding office/outpatient E/M visit levels 2 through 5 in particular, because CPT does not define these codes as clinical staff codes and instead designed them to be directly furnished and reported by physicians and other QHPs, they cannot be used to bill the PFS for services performed by a pharmacist on an ''incident to'' basis. We understand and appreciate the expanding, beneficial roles certain pharmacists play, particularly by specially trained pharmacists with broadened scopes of practice in certain states, commonly referred to as collaborative practice agreements. We note that new coding might be useful to specifically identify these particular models of care.

4. Provision of Maintenance Therapy by Therapy Assistants

a. Finalization of the Interim Final Rule Related to Provision of Maintenance Therapy by Therapy Assistants During the PHE for COVID–19

As a means of increasing the availability of needed health care services during the PHE for COVID–19, we amended our therapy policy on an interim basis in the May 8th COVID–19 IFC (85 FR 27550 through 27629) to allow physical therapists (PT) and occupational therapists (OT) that have established a therapy maintenance program for a patient to assign a PTA or OTA to furnish the maintenance therapy services when clinically appropriate. We indicated as part of the CY 2021 PFS proposed rule that we would respond to comments we received in response to our amended policy for the provision of maintenance therapy services.

Comment: We received several comments, all of which expressed support for allowing therapy assistants to furnish maintenance therapy when delegated by a therapist, including one commenter that requested the CMS make the change permanent.

Response: We appreciate the commenters' support for our adopted interim policy to allow therapy assistants to furnish maintenance therapy services.

After considering comments, we are finalizing our interim policy from the May 8th COVID–19 IFC to allow physical and occupational therapists to delegate maintenance therapy services to therapy assistants as clinically appropriate through the end of the PHE for COVID–19.

b. Summary of Proposals and Public Comments Related to Provision of Maintenance Therapy by Therapy Assistants

In response to our request for feedback on scope of practice (noted above), consistent with E.O. 13890 (84 FR 53573 through 53576), respondents requested that we allow physical therapy assistants (PTAs) and occupational therapy assistants (OTAs) to furnish maintenance therapy services associated with a maintenance therapy program. Respondents commented that our Part B therapy policy was not consistent with policies for these services when provided to patients in skilled nursing facilities (SNF) and home health (HH) settings paid under Part A. Respondents also wrote that because a therapist is responsible for a patient's care over an episode, that this should allow the therapist to assign responsibility for maintenance therapy to an assistant when it is clinically appropriate. Some respondents stated that permitting PTAs and OTAs to furnish maintenance therapy services would give Medicare patients greater access to care and give therapists more flexibility in allocating therapy resources.

After considering respondents' concerns about the incongruity between our Part B and Part A maintenance therapy policies and as a means of increasing availability of needed health care services during the PHE for COVID–19, we amended our policy on an interim final basis in the May 8th COVID–19 IFC (85 FR 27550 through 27629) to allow the physical therapist (PT) or occupational therapist (OT) who establishes a maintenance program to assign a PTA or OTA to furnish maintenance therapy services when clinically appropriate.

We explained that making this change could free-up the PT or OT to furnish other services, particularly services related to the PHE for COVID–19 that require a therapist's assessment and intervention skills. We stated explicitly that the maintenance therapy services furnished by therapist-supervised OTAs and PTAs will be paid in the same manner as those we already pay for as rehabilitative therapy services. We referred readers to regulatory payment conditions for Part B outpatient occupational and physical therapy services (§§ 410.59 and 410.60, respectively) that require, as a basic rule, that the services be provided by an individual meeting qualifications in 42 CFR part 484 for an OT or PT, or an appropriately supervised OTA or PTA.

In the CY 2021 PFS proposed rule, we proposed to make permanent our Part B policy for maintenance therapy services effective January 1, 2021 in order to create greater conformity in payment policy for maintenance therapy services that are furnished and paid under Part B with those in SNF and HH settings under Part A. We noted that if finalized, our policy would dovetail with our

[21] CPT 2021 Professional Edition, p. xiv.

[22] CPT 2021 Professional Edition, pp.14–17.

[23] CPT 2021 Professional Edition, p.818.

amended policy set forth in the May 8th COVID–19 IFC (85 FR 27550 through 27629) that grants PTs and OTs the discretion to delegate maintenance therapy services to the PTAs and OTAs, as clinically appropriate, for the duration of the PHE for COVID–19. If the PHE for COVID–19 were to end prior to January 1, 2021, the therapist would need to personally furnish the maintenance therapy services until the finalized policy change took effect. We also noted that we planned to address comments from the May 8th COVID–19 IFC in conjunction with the comments from the CY 2021 PFS proposed rule in the CY 2021 PFS final rule.

Our policy for maintenance therapy services is explained in section 220.2 of chapter 15 of the Medicare Benefit Policy Manual (see *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*). Maintenance programs that can be carried out by a patient alone or with the assistance of caregivers are not covered. Also, sections 230.1 and 230.2 of chapter 15 of the Medicare Benefit Policy Manual specify that a PTA or OTA may not provide skilled maintenance program services.

In considering this proposal, we reviewed regulatory requirements for conditions of payment for outpatient occupational therapy, physical therapy, and speech-language pathology services at §§ 410.59, 410.60, and 410.62; the regulation for therapy treatment plans at § 410.61; and the regulations specifying treatment plan certification and recertification requirements at § 424.24 for Part B occupational therapy, physical therapy, and speech-language pathology services along with the above mentioned manual provisions.

Given that we already make payment for rehabilitative services requiring improvement in the patient's functional status when they are furnished by PTAs and OTAs at the discretion of the supervising therapist treating the patient in accordance with the therapist-established plan of care, we noted that it would be appropriate for the therapist to use that same judgment to decide whether to delegate maintenance therapy services under the associated plan of care to a PTA or OTA. We stated that there is little difference between the rehabilitative therapy services furnished to improve a patient's functional status and those for maintenance therapy services other than the goals set by the therapist in the therapy plan. We do not believe that the therapist-only maintenance therapy requirement is needed in the case of outpatient physical or occupational therapy services. Instead, we believe that it would be appropriate for an OT or PT to use their professional judgment to assign the performance of maintenance therapy services to an OTA or PTA when it is clinically appropriate to do so.

As such, we proposed to allow, on a permanent basis, therapists to delegate performance of maintenance therapy services to an OTA or PTA for outpatient occupational and physical therapy services in Part B settings beginning January 1, 2021. This proposal would better align our Part B policy with that in SNFs and HH paid under Part A where maintenance therapy services may be performed by a therapist or a therapy assistant. Since our regulations at §§ 410.59, 410.60, 410.61, 410.62, and 424.24, do not distinguish between rehabilitative and maintenance therapy services, we did not propose to amend them. Instead, we proposed to revise sections 220.2, 230.1 and 230.2 of chapter 15 of the Medicare Benefit Policy Manual to clarify that PTs and OTs no longer need to personally perform maintenance therapy services and to specifically remove the prohibitions on PTAs and OTAs from furnishing such services. We noted that we believe the proposal to allow PTs and OTs to delegate maintenance therapy services to their supervised assistants is in keeping with E.O. 13890 and appeals by respondents to our request for feedback on scope of practice that followed, rather than the alternative option of maintaining the pre-COVID–19 policy of requiring PTs and OTs to personally furnish them, after the PHE for COVID–19 has ended.

We noted also that therapists and therapy providers should consult the CQ and CO modifier policies to consider whether these modifiers should be applied to claims for services furnished in whole or in part by PTAs and OTAs which will, beginning January 1, 2022, be paid at 85 percent of the amount that would otherwise apply for the service, as required by section 1834(v) of the Act, which was added to section 53107 of the Bipartisan Budget Act of 2018. See the CY 2020 PFS rulemaking for policies related to the application of CQ and CO modifiers and the associated regulatory requirements (84 FR 40558 through 40564 (proposed rule) and 84 FR 62702 through 60708 (final rule)).

We received public comments on the provision of maintenance therapy to be furnished by therapy assistants. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed uniform support for our proposal to allow therapy assistants to furnish maintenance therapy services. Commenters indicated that having Part B policy align with current Part A policy for Home Health and SNF settings will promote consistency as well as continuity of care across Medicare programs.

Response: We appreciate the commenters' support for our proposal to allow therapy assistants to furnish maintenance therapy services. After considering comments, we are finalizing our proposal to allow physical and occupational therapists to delegate maintenance therapy services to therapy assistants on a permanent basis as clinically appropriate.

5. Medical Record Documentation

a. Finalization of Interim Final Rule With Comment Period Provisions Related to Therapy Student Documentation During the PHE for the COVID–19 Pandemic

In the May 8th COVID–19 IFC (85 FR 27556 through 27557), to increase the availability of clinicians who may furnish healthcare services during the PHE, we announced a general policy that there is broad flexibility for all members of the medical team to add documentation in the medical record which is then reviewed and verified (signed) by the appropriate clinician. Specifically, we stated on an interim basis during the PHE for COVID–19, any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date), rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We noted that although there are currently no statutory or regulatory documentation requirements that would impact payment for therapists when documentation is added to the medical record by persons other than the therapist, we discussed this issue in response to stakeholder concerns about burden and in consideration of the current PHE for COVID–19. Specifically, this policy will ensure that therapists, as members of the clinical workforce, are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. We emphasized that our established principle is focused on the

clinician, as described above who furnishes and bills for their professional services rather than the individuals who may enter information into the medical record. We emphasized that information entered into the medical record should document that the furnished services are reasonable and necessary.

We received public comments on Therapy Student Documentation. The following is a summary of the comments we received and our responses.

Comment: One commenter recommended that CMS make the therapy student documentation waiver under the PHE for COVID–19 permanent so that it aligns with the flexibility extended to physicians and several NPPs as promulgated in the CY 2020 PFS final rule.

Response: We appreciate the commenter's support of this provision for student documentation and making permanent the broad flexibility for all members of the medical team to add documentation in the medical record which is then reviewed and verified (signed) by the appropriate clinician.

Comment: One commenter supported these changes which will give more flexibility to practitioners and other providing clinically appropriate therapy services but asked that CMS clarify who would be considered other members of the ''treatment team'' in addition to those enumerated (that is, physicians, residents, nurses, and students)—in particular, whether this would encompass non-licensed member.

Response: We appreciate the commenters request for clarification. Any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team), or other members of the medical team.

Comment: One commenter agreed with CMS that these measures should be temporary, and should not persist once the PHE for COVID–19 has ended. The commenter stated that training-appropriate scope of practice standards are important to ensuring quality of care for our members.

Response: We appreciate the commenter's feedback. We are discussing this issue in response to stakeholder concerns about burden and in consideration of the current PHE for COVID–19. Specifically, this policy will ensure that therapists, as members of the clinical workforce, are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. The provision related to therapy student documentation was to increase the availability of clinicians who may furnish healthcare services during the PHE for COVID–19 and on an interim basis during the PHE for COVID–19.

In summary, we reiterate that our clarification about this policy as discussed in the May 8th COVID–19 IFC (85 FR 27556 through 27557) notes that any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date), rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We emphasized that our established principle is focused on the clinician, as described above who furnishes and bills for their professional services rather than the individuals who may enter information into the medical record. We emphasized that information entered into the medical record should document that the furnished services are reasonable and necessary.

b. Medical Record Documentation Clarification

As we established in the CY 2020 PFS final rule (84 FR 62681 through 62684), and similarly expressed in the May 8th COVID–19 IFC (85 FR 27556 through 27557), any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We noted that although there are currently no documentation requirements that would impact payment for PTs, OTs, or SLPs when documentation is added to the medical record by persons other than the therapist, we are responding in this proposed rule to stakeholder requests for clarification. Specifically, we clarified that the broad policy principle that allows billing clinicians to review and verify documentation added to the medical record for their services by other members of the medical team also applies to therapists. We noted that this would help ensure that therapists are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. We emphasized that, while any member of the medical team may enter information into the medical record, only the reporting clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills. We also emphasized that information entered into the medical record should document that the furnished services are reasonable and necessary.

We received public comments on the medical record documentation clarification. The following is a summary of the comments we received and our responses.

Comment: Many commenters were in support of and commended CMS for including therapists in the list of practitioners who may review and verify documentation instead of having to re-document notes made by students for Medicare Part B patients and stated that this is a significant burden reduction that will allow for better use of therapists' time.

Two commenters appreciated this medical record documentation flexibility so long as the provision falls within existing scope of practice laws and only reduces the burden of re-documenting. The commenter noted that administrative burden is a major reason for physician burnout and by alleviating this burden and allowing others to share in the administrative process, physicians will spend less time documenting and perhaps have a decrease in burnout. Another commenter noted in rural areas, there are shortages of therapy and mental health professionals and that documentation and paperwork take time away from patients who need help.

A few commenters noted that this flexibility would better prepare clinicians to enter practice by increasing safety and education on how to document effectively and appropriately the skilled services they provide. One commenter questioned how this flexibility may impact documentation requirements pertaining to completion of the progress report and Medicare's billing rules in relation to therapy students. Another commenter requested licensed audiologists be added to the group that can review and verify (sign and date) the documentation entered into the medical record by members of

their medical team for their own, appropriately supervised services that are paid under the PFS.

One commenter requested that CMS issue guidance to clarify that it is possible that no additional documentation is required if the entirety of the documentation could be included from members of the medical team, thus allowing the billing practitioner to ''sign and verify'' the entire note.

Response: We appreciate commenters' support of this clarification to allow therapists to review and verify student documentation instead of therapists having to re-document notes made by students. We appreciate the insight provided by commenters about how the broad flexibility would aide in burden reduction and allow for better use of time by therapists.

This clarification similarly aligns with what was finalized in the CY 2020 PFS final rule which provided broad flexibility to the physicians, PAs and APRNs (regardless of whether they are acting in a teaching capacity) who document and who are paid under the PFS for their professional services. We explained that this principle would apply across the spectrum of all Medicare-covered services paid under the PFS. We emphasize that, while any member of the medical team may enter information into the medical record, only the billing clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills. As we emphasized in our proposal, information entered into the medical record should document that the services furnished are reasonable and necessary if the billing practitioner has signed and verified complete medical record documentation by other members of the medical team.

Comment: One commenter supported the CMS policy to provide added flexibility for NPPs authorized to deliver part B services including nurse practitioners, CNSs and PAs to document teaching physician involvement and another commenter noted they believe that the additional flexibility will significantly reduce burden for teaching physicians.

Response: We appreciate the support of this flexibility for NPPs to document teaching physician involvement. We would like to reiterate that this flexibility does not negate the teaching physician rules, or the need to document personal services or split share rules, or other aspects of the service provided.

Comment: One commenter urged CMS not to expand payment for independent NPPs and pressure inappropriate scope-of-practice expansion through these proposed rules. The commenter encouraged all advanced nurse practitioners and physician assistants to work within their respective licensed scope of practice in a team approach to expand access and ensure quality of care. Another commenter expressed concern that based on the language proposed by CMS, this policy might allow therapists to change or modify a physician's documentation, including their diagnostic evaluation and treatment plan.

Response: We appreciate the commenters concerns and want to emphasize that this medical record documentation clarification only applies to the clinician who is billing for their professional service. The intent of this clarification is to reduce burden and allow the billing practitioner to review and verify the documentation in the medical record instead of re-documenting information entered by students and other members of the medical team. The billing practitioner needs to ensure, as we reiterated in our clarification, that, while any member of the medical team may enter information into the medical record, they review and verify that the information in the medical record is accurate and complete for the services the reporting clinician furnishes and bills.

After considering the comments received, we note that we are reiterating what we finalized in the CY 2020 PFS final rule, that any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We emphasize that, while any member of the medical team may enter information into the medical record, only the reporting clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills. We want to emphasize that information entered into the medical record must document that the furnished services are reasonable and necessary.

H. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of

new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the federal government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and

developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2021 PFS proposed rule and those comments are summarized below.

Comment: Several commenters disagreed with our reference to older work time sources, and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times. It also would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional

information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs.

We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this current CY 2021 PFS final rule, CPT codes 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) and 57465 (*Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect*), 76513 (*Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy, unilateral or bilateral*), 93224 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional*) and 99439 *(Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes*) share the identical total work time of 15 minutes. However, these codes have very different proposed work RVUs of 1.00 and 0.81 and 0.53 and 0.39 and 0.61 respectively. In addition, CPT codes 10010 (*Fine needle aspiration biopsy, including CT guidance; each additional lesion*) and 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation*) both share the same intraservice and total work time of 25 minutes but each code has a different work RVU. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors employed in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

We also want to clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regard to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters discouraged the use of valuation based on work RVU increments. Commenters stated that this methodology inaccurately treats all components of the physician time as having identical intensity and would lead to incorrect work valuations. Commenters stated that CMS should carefully consider the clinical information justifying the changes in physician work intensity provided by the RUC and other stakeholders.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also

used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters stated that they were concerned about CMS' lack of consideration for compelling evidence that services have changed. Commenters stated that CMS appeared to dismiss the fact that services may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services. Commenters requested that CMS address the compelling evidence that was submitted with the RUC recommendations when the agency does not accept the RUC recommendation.

Response: The concept of compelling evidence was developed by the RUC as part of its review process for individual codes to justify an increase in valuation. The RUC's compelling evidence criteria include documented changes in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the service. While we appreciate the submission of this additional information for review, we emphasize that compelling evidence is a concept developed by the RUC for its own review process. Compelling evidence is not part of our statutory framework which requires that the valuation of codes should be based on time and intensity. We do consider changes in technology, patient population, etc. insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation process stipulated by statute.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. We also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 28 contains a list of codes and descriptors for which we proposed work RVUs; this included all codes for which we received RUC recommendations by February 10, 2020. As noted in the CY 2021 PFS proposed rule, the proposed work RVUs, work time and other payment information for all CY 2021 payable codes are available on the CMS website under downloads for the CY 2021 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 29 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of the proposed rule (85 FR 50077), Determination of Practice Expense Relative Value Units (PE RVUs), we addressed certain refinements that would be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We noted that for each refinement, we indicated the impact on direct costs for that service. We noted that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also noted that approximately half of the refinements listed in Table 29 result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

We also noted that the direct PE inputs for CY 2021 are displayed in the CY 2021 direct PE input files, available on the CMS website under the downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* The inputs displayed there have been used in developing the CY 2021 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We noted that we believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of the proposed rule (85 FR 50077), Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2021 we received invoices for several new supply and equipment items. Tables 31 and 32 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of the proposed rule (85 FR 50077), Determination of Practice Expense Relative Value Units, we encouraged stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encouraged stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 31 and 32 also included the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we did not use the price listed on the invoice that

accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We addressed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We noted that the public use files for the PFS proposed and final rules for each year display the services subject to the MPPR for diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. We also include a list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2021 are available on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

4. Proposed Valuation of Specific Codes for CY 2021

(1) Fine Needle Aspiration (CPT Codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, and 10012)

In June 2017, the CPT Editorial Panel deleted CPT code 10022, revised CPT code 10021, and created nine new codes to describe fine needle aspiration procedures with and without imaging guidance. These ten codes were surveyed and reviewed for the October 2017 and January 2018 RUC meetings. In the CY 2019 PFS final rule, we finalized the RUC-recommended work RVU for seven of the ten codes in the family, while finalizing a lower work RVU for CPT codes 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*), 10009 (*Fine needle aspiration biopsy, including CT guidance; first lesion*), and 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*). For a full discussion of this review, we refer readers to the CY 2019 PFS final rule (83 FR 59517 through 59521).

Following the publication of the CY 2019 PFS final rule, RUC staff stated that CMS erroneously double-counted the utilization for new codes that had image guidance bundled. We disagreed that this constituted a technical error and communicated to the RUC in conversations following the publication of the rule that the surveying specialties could instead nominate the affected codes from these families as being potentially misvalued. At the January 2020 RUC meeting, the RUC reaffirmed its CY 2019 recommendations for physician work and direct PE for the ten codes in the Fine Needle Aspiration code family.

In discussing this group of codes, we would like to clarify again that we disagree with the RUC and do not believe that utilization was erroneously double-counted for this code family. We publish our proposed utilization crosswalk each year as a public use file available on the CMS website; the current such file is available under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. During the CY 2019 rule cycle, we proposed the utilization crosswalk for the Fine Needle Aspiration family as it was recommended to CMS by the RUC, and we did not receive any comments on this subject until after the valuation of these codes had been finalized. We proposed and finalized the utilization crosswalk for this code family as recommended by the RUC without receiving any comments from the RUC or other stakeholders. If the RUC or other stakeholders believed that what CMS had proposed was incorrect or misunderstood what the RUC had recommended, there was an opportunity to comment during the 60 days following the publication of the proposed rule. We disagreed that the utilization crosswalk was erroneous, and we did not make a technical correction following the publication of the CY 2019 PFS final rule for this reason.

We also disagreed with the RUC that the utilization crosswalk was ''the principle reason CMS rejected the RUC recommendations'' for the codes in the Fine Needle Aspiration family, as stated in the RUC's CY 2021 recommendations for this code family. As we stated in the CY 2019 PFS proposed rule and restated in the CY 2019 PFS final rule, our refinements to the work RVUs of CPT codes 10021, 10005, and 10009 were primarily based on changes in surveyed work time and the relationship between the codes in the family. For example, this was our rationale for refining the work RVU of CPT code 10021 from the RUC-recommended value of 1.20 to the finalized value of 1.03: In reviewing CPT code 10021, we noted that the recommended intraservice time is decreasing from 17 minutes to 15 minutes (12 percent reduction), and the recommended total time is decreasing from 48 minutes to 33 minutes (32 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.27 to 1.20, which is a reduction of just over 5 percent. In the case of CPT code 10021, we believed that it was more accurate to propose a work RVU of 1.03 based on a crosswalk to CPT code 36440 to account for these decreases in the surveyed work time (83 FR 59518). We noted that this primary rationale for refining the work RVU did not mention the utilization crosswalk at all.

When we communicated to the RUC following the publication of the CY 2019 PFS final rule that the codes in the Fine Needle Aspiration family could be nominated as potentially misvalued, we indicated that we were open to receiving new information about the valuation of these codes. In reaffirming its recommendations from CY 2019, however, the RUC has not provided any

new information that was not already presented for the previous CMS review of these codes. Therefore, we did not propose any changes to the codes in the Fine Needle Aspiration family, as the reaffirmed CY 2021 RUC recommendations are identical to the CY 2019 RUC recommendations that already went through notice and comment rulemaking. We welcomed the submission of new information regarding these services that was not part of the previous CY 2019 review of the code family.

We received public comments on the Fine Needle Aspiration code family. The following is a summary of the comments we received and our responses.

Comment: Several commenters maintained that CMS inadvertently double counted each bundled image guidance code during their RUC recommendation evaluation in CY 2019 due to a misinterpretation of the RUC's utilization crosswalk recommendations. Commenters stated that after correcting for double counting the utilization for the newly created bundled codes, the work pool based on the RUC-recommended values would have instead resulted in a decrease by 15 percent using the CMS utilizations from the CY 2019 PFS proposed rule. Commenters stated that based on the CMS proposed reductions, the work pool for the family would decrease by 23 percent based on the utilization data available during the CY 2019 rulemaking.

Response: As we stated in the CY 2021 PFS proposed rule (85 FR 50152), we continue to disagree with the RUC and do not believe that utilization was erroneously double-counted for this code family. We proposed and finalized the utilization crosswalk for this code family as recommended by the RUC without receiving any comments from the RUC or other stakeholders and we did not make a technical correction following the publication of the CY 2019 PFS final rule for this reason.

Comment: Several commenters stated that they had new information to provide based on reviewing actual claim data from CY 2019 to assess the accuracy of the RVU pool estimates during the CY 2019 rulemaking process. Commenters stated that CMS' projected RVU pool for CY 2019 for the updated Fine Needle Aspiration code family was over twice as high as what actually occurred in 2019 even though the utilization for the newly created codes is largely identical to the source utilization from CPT codes 10021 and 10022. Commenters recommended CMS to finalize the RUC-recommended work RVUs for CPT codes 10005, 10009, and 10021.

Response: We appreciate the additional information provided by the commenters in their review of the claims data from CY 2019. However, we note that it is not typically part of our methodology to review the accuracy of the RUC-recommended utilization crosswalk against the claims data when it becomes available 2 years later. Historically, there have been many times when the projected crosswalk overestimated utilization for a new service. Also, there have been many times when the projected crosswalk underestimated utilization. In the absence of a systematic process to investigate the accuracy of these projected utilization crosswalks across a broad range of services, we do not believe that it would serve the interests of relativity to single out individual code families and compare them against their projected crosswalks. It would distort relativity to conduct this analysis in situations where it might be advantageous for valuation while failing to conduct the same analysis in situations where it might be disadvantageous.

More importantly, we continue to disagree with the RUC that the utilization crosswalk was ''the principle reason CMS rejected the RUC recommendations'' for the codes in the Fine Needle Aspiration family, as stated in the RUC's CY 2021 recommendations for this code family. As we stated in the CY 2019 PFS proposed rule, restated in the CY 2019 PFS final rule, and again restated in the CY 2021 PFS proposed rule, our refinements to the work RVUs of CPT codes 10021, 10005, and 10009 were primarily based on changes in surveyed work time and the relationship between the codes in the family. We noted that this primary rationale for refining the work RVU did not mention the utilization crosswalk at all. We continue to believe that the changes in surveyed work time and the relationship between the codes in the family support the work valuations finalized in CY 2019 rulemaking.

Comment: Several commenters disagreed with the rationale provided by CMS when the work RVUs for these codes were finalized in CY 2019 rulemaking. Commenters stated that CMS continued to use intraservice time ratios to revalue codes and then applied inappropriate crosswalks to justify their logic. Commenters stated that the CMS crosswalk codes, such as CPT code 36440 (*Push transfusion, blood, 2 years or younger*), are not clinically similar to the reviewed codes including the associated risks and required decision-making. Commenters stated that the work RVU for CPT code 10005 could be more appropriately crosswalked to CPT code 76978 (*Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion*) based on the identical intraservice work time, intensity, complexity similarities, and ultrasound service similarities. Commenters similarly stated that the work RVU of CPT code 10021 could be more accurately crosswalked to CPT code 95866 (*Needle electromyography; hemidiaphragm*). Commenters again suggested CMS to finalize the RUC's reaffirmed work RVUs for these services.

Response: We disagree with these valuation suggestions presented by the commenters as they reiterate the same arguments that we considered and ultimately did not finalize when the codes in the Fine Needle Aspiration were previously reviewed. For a full discussion of this subject, we direct readers to the CY 2019 PFS final rule (83 FR 59517–59521). We continue to believe that the changes in surveyed work time and the relationship between the codes in the family support the work valuations finalized in CY 2019 rulemaking.

Comment: Several commenters stated that for several equipment items, including the mayo stand (EF015), the exam table (EF023), and the portable ultrasound unit (EQ250), it appeared that there was a calculation error in CMS' direct PE refinement table. Commenters provided a spreadsheet which clarified the RUC's comments on individual refinements of direct PE inputs with suggested equipment times for these items.

Response: We disagree with the commenters and we continue to believe that the equipment times finalized in CY 2019 rulemaking are correct. The finalized equipment times for these three equipment items conform to the standard established policies for non-highly technical equipment. The equipment times recommended by the commenters do not conform to these standard equipment time formulas, instead adding additional time for the ''Complete post-procedure diagnostic forms, lab and x-ray requisitions'' (CA027) and ''Review home care instructions, coordinate visits/prescriptions'' (CA035) clinical labor activities. In particular, we note that the CA035 clinical labor activity is not part of the standard established policies for non-highly technical equipment formula; the RUC has mistakenly labeled it as such on some of their recommended PE spreadsheets. Since

these clinical labor activities are not part of the standard equipment time formula, and we have no reason to believe that they would be typical for the services in question; we continue to believe that the equipment times finalized in CY 2019 rulemaking are correct.

We did not propose any changes to the codes in the Fine Needle Aspiration family and although we appreciate the information supplied by the commenters, we are not finalizing any changes to these services. In the event that there is a new review of these services, as opposed to a reaffirmation of the previous review, we would look forward to receiving any additional information or new data.

(2) Tissue Expander Other Than Breast (CPT Code 11960)

This service was included in a larger group of similarly related codes that were recommended for review for the October 2019 RUC meeting. The RUC recommended re-reviewing this code at a more granular level for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 12.40 for CPT code 11960 (*tissue expander other than breast*). We proposed to maintain the current work RVU of 11.49 supported by a reference code, CPT code 45560 (*repair of rectocele (separate procedure)*), which has a work RVU of 11.50. CPT code 45560 shares the same intraservice time of 90 minutes with CPT code 11960 and has a slightly higher total time of 367 minutes. The recommended total time for CPT code 11960 decreased from 444 minutes to 357 minutes, with a slight increase in intraservice time of 78 minutes to 90 minutes. We noted that we believe the similar work RVU of the reference CPT code 45560, as well as the reduction in total time, supports maintaining the current work RVU of 11.49 for CPT code 11960. We proposed the RUC-recommended direct PE inputs for CPT code 11960 without refinements.

We received public comments on the Tissue Expander Other Than Breast.

The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the proposal to maintain the current work RVU of 11.49 for CPT code 11960 (*Tissue expander other than breast*) and stated that CMS should finalize the RUC-recommended work RVU of 12.40. In particular, commenters stated they believe that there is an anomalous relationship between current work RVU and current physician time reflected in an inappropriate intensity. The commenters also believe that we have not appropriately accounted for the RUC-recommended increase in intraservice time.

Response: We acknowledge that the RUC recommended an increase in intraservice time. However, we believe that when our review of recommended values reveals changes in time that have been unaccounted for in a recommended RVU, such as in the decrease of total time unaccounted for with CPT code 11960, we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. To validate further our valuations for work RVUs, we incorporate multiple methodologies, which also consider intensity of the service. For additional information regarding our use of methodologies for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: Commenters stated that they disagree with our use of the chosen reference code, CPT code 45560 (*Repair of rectocele (separate procedure)*). Commenters stated that they believe the chosen reference code does not accurately support the proposed work times for this code because it is ''low volume'' and it has been too long since the last survey to be an accurate comparison for determining an appropriate valuation. The commenters also stated that there is no evidence to support a clinical comparison between CPT code 11960 and the chosen reference code.

Response: We consider reference codes as supportive of a code valuation rather than as a direct ''cross-walk.'' CPT code 45560 has a work RVU of 11.50. It shares the same intraservice time of 90 minutes with CPT code 11960 and has a slightly higher total time of 367 minutes. We do not agree that codes must share the same patient population or utilization level to serve as an appropriate reference code. We also recognize that it is important to use recent data available regarding work times. However, we believe that while some reference codes may not have been recently surveyed, they still provide support for revision of work RVUs when survey times show a marked decrease in time.

After consideration of these public comments, we are finalizing the work RVU and direct PE inputs for CPT code 11960 as proposed.

(3) Breast Implant-Expander Placement (CPT Codes 11970, 19325, 19340, 19342, and 19357)

These services were included in a larger group of 22 breast reconstruction and similarly related codes that were recommended for survey for the October 2019 RUC meeting. At the October 2019 RUC meeting, these codes were recommended for a more granular review for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 8.01 for CPT code 11970 (*replacement of tissue expander with permanent implant*). We proposed a work RVU of 7.49 supported by a reference code CPT code 35701 (*exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian)*), which has a work RVU of 7.50. CPT code 35701 shares the same intraservice time of 60 minutes with CPT code 11970 and has a slightly higher total time of 229 minutes as compared to 216 minutes. In addition, during our review of CPT code 11970, we noted that the recommended intraservice time is decreasing from 78 minutes to 60 minutes and the recommended total time of 231 minutes is decreasing to 216 minutes. We also noted that the proposed work RVU of 7.49 for CPT code 11970 is equal to the total time ratio amount, which is the current total time compared to the RUC-recommended total time. We proposed the RUC-recommended direct PE inputs for CPT code 11970.

We disagreed with the RUC-recommended work RVU of 8.64 for CPT code 19325 (*breast augmentation with implant*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 11970 and 19325 is equivalent to the RUC-recommended interval of 0.63 RVUs. Therefore, we proposed a work RVU of 8.12 for CPT code 19325, based on the RUC-recommended interval of 0.63 additional RVUs above our proposed work RVU of 7.49 for CPT code 11970. We noted that we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We also supported the proposed work RVU of 8.12 based on a reference code, CPT code 25652 (*open treatment of ulnar styloid fracture*). CPT code 25652 shares the same intraservice time of 60 minutes and the same total time of 225 minutes with a lower work RVU of 8.06. In addition, during our review of CPT code

19325, we noted that the total time has decreased from 244 minutes to 225 minutes and the intraservice time has decreased from 90 minutes to 60 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19325.

We disagreed with the RUC-recommended work RVU of 11.00 for CPT code 19340 (*insertion of breast implant on same day of mastectomy (i.e. immediate)*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 19325 and 19340 is equivalent to the RUC-recommended interval of 2.36 RVUs. Therefore, we proposed a work RVU of 10.48 for CPT code 19340, based on the recommended interval of 2.36 additional RVUs above our proposed work RVU of 8.12 for CPT code 19325. We also supported our proposed work RVU of 10.48 based on a reference code, CPT code 47562 (*laparoscopy, surgical; cholecystectomy*). CPT code 47562 shares the same intraservice time of 80 minutes and only a slightly lower total time of 251 minutes with a similar work RVU of 10.47. In addition, during our review of CPT code 19340, we noted that the total time has decreased from 366 minutes to 261 minutes and the intraservice time has decreased from 120 minutes to 80 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19340.

We disagreed with the RUC-recommended work RVU of 11.00 for CPT code 19342 (*insertion or replacement of breast implant on different day from mastectomy*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 19325 and 19342 is equivalent to the RUC-recommended interval of 2.36 RVUs. Therefore, we proposed a work RVU of 10.48 for CPT code 19342, based on the recommended interval of 2.36 additional RVUs above our proposed work RVU of 8.12 for CPT code 19325. We also noted that the RUC-recommended work RVU of 11.00 is equal to the RUC-recommended work RVU for CPT code 19340 because they have stated that both services involve an identical amount of physician work and similar times. We also supported our proposed work RVU of 10.48 based on a reference code, CPT code 47562 (*laparoscopy, surgical; cholecystectomy*). CPT code 47562 shares the same intraservice time of 80 minutes and only a slightly lower total time of 251 minutes with a similar work RVU of 10.47. The total time for CPT code 19342 has decreased from 320 minutes to 252 minutes and the intraservice time has decreased from 115 minutes to 80 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19342.

We disagreed with the RUC-recommended work RVU of 15.36 for CPT code 19357 (*tissue expander placement in breast reconstruction, including subsequent expansion*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 11970 and 19357 is equivalent to the RUC-recommended interval of 7.35 RVUs. Therefore, we proposed a work RVU of 14.84 for CPT code 19357, based on the recommended interval of 7.35 additional RVUs above our proposed work RVU of 7.49 for CPT code 11970. We also supported our proposed work RVU of 14.84 based on a reference code, CPT code 37605 (*ligation; internal or common carotid artery*). CPT code 37605 shares the same intraservice time of 90 minutes and only a slightly lower total time of 342 minutes with a lower work RVU of 14.28. In addition, during our review of CPT code 19357, we noted that the total time has decreased from 468 minutes to 344 minutes and the intraservice time has decreased from 110 minutes to 90 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19357.

We received public comments on the Breast Implant-Expander Placement code family. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with the proposed work RVU of 7.49 for CPT code 11970 and stated that CMS should finalize the RUC-recommended work RVU of 8.01. Commenters stated that they disagree with the use of the total time ratio methodology for the valuation of this code. The commenters stated that they believe the total time ratio is invalid because it uses 30-year-old total time from the Harvard Study. Additionally, commenters stated that they believe CMS did not consider intensity of the service while using this methodology, which they believe is actually much higher than what CMS has accounted for. Commenters stated that they believe CMS substituted an arbitrary determination of work values derived from time and a subjective estimate of intensity based on an unknown and clinically uniformed opinion.

Response: We disagree and continue to believe that the use of time ratios is an appropriate method for identifying potential work RVUs for particular PFS services. In regard to the age of the data from the Harvard study, if we were to operate under the assumption that previously recommended work times are now arbitrarily invalid, this would undermine the relativity of the work RVUs on the PFS in general, given that codes are, and have been over many years, often valued by comparisons to codes with similar times. For CPT code 11970, survey times showed a total time and intraservice time decrease. Therefore, we believe the total time ratio, as a comparison of the current work time versus the RUC-recommended work times, is an appropriate methodology to value the work for this CPT code. For additional information regarding our use of time ratios for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: Commenters disagreed with the proposed work RVU of 8.12 for CPT code 19325 and stated that CMS should finalize the RUC-recommended work RVU of 8.64. Commenters also disagreed with the proposed work RVU of 10.48 for CPT code 19340 and CPT code 19342 and stated that we should finalize the RUC-recommended work RVU of 11.00 for both CPT codes. Commenters also stated that they disagreed with the proposed work RVU of 14.84 for CPT code 19357 and stated that instead we should finalize the RUC-recommended work RVU of 15.36. Commenters stated that they do not support the use of an incremental methodology as an appropriate method for identifying work RVUs for these PFS services. In particular, commenters noted that they believe this methodology adds fragility to the relative value system, as an error in the foundation code could affect the entire code family.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. For additional information regarding

our use of an incremental difference for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: Commenters disagreed with our use of the chosen supporting reference codes throughout the code family. For CPT code 11970, CPT code 19325, and CPT code19357, commenters stated that they believe the chosen reference codes are too ''low-volume'' to accurately support the proposed work times for these codes. Additionally, commenters stated that for CPT code 19325, CPT code 19340, CPT code 19342, and CPT code 19357, that the work values for the reference codes chosen by CMS are too old to be accurate comparisons for determining appropriate valuations. The commenters also stated that several of the reference codes are not relevant for purposes of valuation because there is no evidence to support clinical comparison.

Response: We are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. Additionally, we use other methods to validate work RVUs, such as reference codes. When using reference codes to support a proposed work RVU, we do not consider them as a direct ''cross-walk'' between the CPT code that is being revalued and the chosen reference code. Instead, a reference code used as a supportive check in validating work times. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparisons to one another. We do not agree that codes must share the same patient population or utilization level to serve as an appropriate reference code. We also recognize that it is important to use the most recent data available regarding work times. However, we believe that while some reference code values may be considered older, they still provide support for revision of work RVUs when survey times show a marked increase or decrease in total and intraservice time, such as was the case for this code family.

Comment: Commenters stated that CMS must ensure that any RVU reduction of more than 19 percent is phased in over 2 years, under 1848(c)(7) of the Act. The commenter stated that the magnitude of the proposed RVU reductions for CPT codes 19340 and 19357 would trigger the phase-in requirements since they would be decreasing by more than 19 percent.

Response: Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. We proposed to exempt all of the CPT codes in the Breast Implant-Expander Placement family from the phase-in of significant RVU reductions required by section 1848(c)(7) of the Act due to the fact that they were designated as ''revised'' codes by CPT as a result of significant revisions to their code descriptors. Since all of the codes in the family fall under the revised designation, the phase-in requirement does not apply to them.

Comment: Commenters stated that they are concerned that reducing reimbursement for the services in this code family could limit access to breast reconstruction following mastectomy. The commenters cited a study done by Kamali P et al., titled: Immediate Breast Reconstruction among Patients with Medicare and Private Insurance: A Matched Cohort Analysis. Commenters also stated that they wanted to bring to our attention the Women's Health and Cancer Rights Act of 1998 (WHCRA). The commenters stated that this act provides coverage protection for patients who choose to have breast reconstruction following a mastectomy.

Response: We remain committed to supporting the health of all Medicare beneficiaries, as well as remaining vigilant in support of all services related to minority and women's health. While the WHCRA (Pub. L. 105–277, Title IX, Oct. 21, 1998) is an important federal law that furthers protections for women's healthcare rights and access to services, we note that Medicare does provide coverage for these important services.

After consideration of these public comments, we are finalizing the work RVU and direct PE inputs for the Breast Implant-Expander

(4) Breast Implant-Expander Removal (CPT Codes 11971, 19328, and 19330)

These services were included in a group of codes that were recommended for survey for the October 2019 RUC meeting as part of a large group of 22 breast reconstruction and similarly related services. At its October 2019 meeting, the RUC agreed that a 22-code family was too expansive. They recommended these codes be re-reviewed as part of a smaller and more granular code family for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 7.02 for CPT code 11971 (*removal of tissue expander w/out insertion of implant*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 11970 and 11971 is equivalent to the RUC recommended interval of 0.99 RVUs. Therefore, we proposed a work RVU of 6.50 for CPT code 11971, based on the recommended interval of 0.99 RVUs below our proposed work RVU of 7.49 for CPT code 11970. We noted that as stated previously, we believed the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within families of similarly revised codes. We also supported our proposed work RVU of 6.50 based on a reference code, CPT code 25671 (*percutaneous skeletal fixation of distal radioulnar dislocation*). CPT code 25671 shares the same intraservice time of 45 minutes and a slightly less total time of 210 minutes with a very similar work RVU of 6.46. In addition, during our review of CPT code 11971, we noted that the total time has decreased from 303 minutes to 215 minutes and the intraservice time has decreased from 90 to 45 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 11971.

We disagreed with the RUC-recommended work RVU of 7.44 for CPT code 19328 (*removal of intact breast implant*). Although we disagreed with the RUC-recommended work RVU, we proposed increasing the current work RVU from 6.48 to 6.92 to account for the increases in total and intraservice time. We also concurred that the relative difference in work between CPT codes 11971 and 19328 is equivalent to the RUC-recommended interval of 0.42 RVUs. Therefore, we proposed a work RVU of 6.92 for CPT code 19328, based on the recommended interval of 0.42 additional RVUs above our proposed work RVU of 6.50 for CPT code 11970. We also supported our proposed work RVU of 6.92 based on a reference code, CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*). CPT code 28289 shares the same intraservice time of 45 minutes and a slightly higher total time of 210 minutes with a very similar work RVU of 6.90. The total time for CPT code 19328 has increased from 173 minutes to 199 minutes and the intraservice time has increased from 38 to 45 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19328.

We proposed the RUC-recommended work RVU of 9.00 for CPT code 19330

(*removal of ruptured breast implant, including implant contents*). The survey total time for CPT code 19330 has increased from 218 minutes to 229 minutes and the intraservice time has increased from 62 minutes to 75 minutes. We also proposed the RUC-recommended direct PE inputs for this code without refinements.

We received public comments on the Breast Implant-Expander Removal code family. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with the proposed work RVU of 6.50 for CPT code 11971 and stated that CMS should finalize the RUC-recommended work RVU of 7.02. Commenters also disagreed with the proposed work RVU of 6.92 for CPT code 19328 and stated that CMS should finalize the RUC-recommended work RVU of 7.44. Commenters stated that they do not support the proposed work RVU because they do not support the use of an incremental methodology as an appropriate tool for valuing services in this code family. In particular, commenters noted that they believe this methodology is further inappropriate because it uses a foundation code that is not within the same code family, which adds further fragility to the use of the incremental methodology for valuation of this code family.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity.

Comment: Commenters disagreed with our use of the chosen supporting reference codes for CPT code 11971 and CPT code 19328. The commenters stated that they believe there is not adequate clinical comparison for the work portion of the service. Commenters also stated that they believe the reference code values are too old because they are from outdated survey results and do not have adequately comparable intensities.

Response: When using referencing codes to support a proposed work RVU, we do not consider them as a direct ''cross-walk'' between the CPT code that is being revalued and the chosen reference code. Instead, reference codes are used as a supportive check in validating work times. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparisons to one another.

After consideration of these public comments, we find the arguments for maintaining consistency in methodology and reducing the risk of anomalies within the valuation of this code family to be compelling. We are finalizing the RUC-recommended work RVU of 7.02 for CPT code 11971 and the RUC-recommended work RVU of 7.44 for CPT code 19328. We are also finalizing the direct PE inputs as proposed.

(5) Modified Radical Mastectomy (CPT Code 19307)

The RUC recommended that CPT code 19307 (*Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle*) be surveyed for the January 2020 RUC meeting for site of service anomaly. The Relativity Assessment Workgroup identified services performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital E/M services within the global period and with 2018 Medicare utilization over 5,000. The RUC recommended lowering the work RVU to 17.99 which is the survey's 25th percentile.

We proposed the RUC-recommended work RVUs of 17.99 for CPT code 19307. We also proposed the RUC-recommended direct PE inputs for this code.

We received public comments on Modified Radical Mastectomy (CPT code 19307). The following is a summary of the comments we received and our responses.

Comment: Commenters were overall in support of CMS proposing the RUC recommendations for this code. One commenter noted strong support for the process and of the RUC. Additionally, the commenters suggested CMS to accept the RUC recommendations to extend the office and outpatient E/M work RVU increases to the office and outpatient visits included in 10- and 90-day globals.

Response: We appreciate the commenters' support for CMS proposing the RUC recommendation for Modified Radical Mastectomy (CPT code 19307) and note the commenters concern with regard to office and outpatient E/M work RVU increases to the office and outpatient visits included in 10- and 90-day global.

After consideration of these public comments, we are finalizing as proposed the RUC-recommended work RVU of 17.99 for CPT code 19307. We are also finalizing as proposed the RUC-recommended direct PE inputs for this code.

(6) Breast Lift-Reduction (CPT Codes 19316 and 19318)

These services were included in a larger code group of similarly related services that were recommended for review for the October 2019 RUC meeting. CPT code 19316 (*mastopexy*) and CPT code 19318 (*Breast reduction*) were then recommended for a more granular review for the January 2020 RUC meeting.

We proposed the RUC-recommended work RVU of 11.09 for CPT code 19316 (*mastopexy*) and 16.03 for CPT code 19318 (*Breast reduction*). We proposed the RUC-recommended direct PE inputs for this code family without refinements.

We did not receive public comments on this code family, and are finalizing as proposed.

(7) Secondary Breast Mound Procedure (CPT Codes 19370, 19371, and 19380)

These services were included in a large group of breast reconstruction codes that were recommended to be surveyed for the October 2019 RUC meeting. At the October 2019 RUC meeting, the RUC concurred with the more granular code families but recommended these codes be re-surveyed for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 10.0 for CPT code 19370 (*Revision of peri-implant capsule, breast, including capsulorrhaphy, and/or partial capsulectomy*). We proposed to maintain the current work RVU of 9.17 based on a supporting reference code, CPT code 28299 (*Correction, hallux valgus (bunionectomy*), with sesamoidectomy, when performed; with double osteotomy, any method), which has a work RVU of 9.29. CPT code 28299 shares a similar intraservice time of 75 minutes with CPT code 19370 and has a slightly higher total time of 256 minutes. In addition, we noted during our review of CPT code 19370 that the recommended total time has increased minimally from 253 minutes to 255 minutes, with a slight decrease in intraservice time of 82 minutes to 78 minutes. We noted that we believe the similar work RVU of the supporting CPT code 28299, as well as the minimal changes in physician work time for CPT code 19370, supports maintaining the current work RVU of 9.17. We proposed the RUC-recommended direct PE inputs for CPT code 19370 without refinements.

We disagreed with the RUC-recommended work RVU of 10.81 for CPT code 19371 (*Peri-implant*

capsulectomy, breast, complete, including removal of all intra-capsular contents). Although we disagreed with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 19370 and 19371 is equivalent to the RUC-recommended interval of 0.81 RVUs. Therefore, we proposed a work RVU of 9.98 for CPT code 19371, based on the recommended interval of 0.81 additional RVUs above our proposed work RVU of 9.17 for CPT code 19370. We noted that as stated previously, we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We also supported our proposed work RVU of 9.98 based on a reference code, CPT code 25628 (*Open treatment of carpal scaphoid (navicular) fracture, includes internal fixation, when performed*). CPT code 25628 shares the same intraservice time of 90 minutes and a slightly higher total time of 277 minutes with a work RVU of 9.67. In addition, during our review of CPT code 19371, we noted that the total time for CPT code 19371 has decreased from 306 minutes to 261 minutes and the intraservice time has decreased from 117 to 90 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19371.

We disagreed with the RUC-recommended work RVU of 12.00 for CPT code 19380 (*Revision of reconstructed breast* (*e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 19371 and 19380 is equivalent to the RUC recommended interval of 1.19 RVUs. Therefore, we proposed a work RVU of 11.17 for CPT code 19380, based on the recommended interval of 1.19 additional RVUs above our proposed work RVU of 9.98 for CPT code 19371. We also supported our proposed work RVU of 11.17 based on a reference code, CPT code 64569 (*Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generato*). CPT code 64569 shares the same intraservice time of 120 minutes and only a slightly higher total time of 312 minutes with a work RVU of 11.0. The total time increased from 277 minutes to 307 minutes and the intraservice time has increased from 89 minutes to 120 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19380.

We received public comments on the Secondary Breast Mound Procedure (CPT codes 19370, 19371, and 19380). The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the proposal to maintain the current work RVU of 9.17 for CPT code 19370 (*Revision of peri-implant capsule, breast, including capsulorrhaphy, and/or partial capsulectomy*) and stated that CMS should finalize the RUC- recommended work RVU of 10.00. Some of the commenters disagreed with comparing the current intraservice time and total time from the Harvard study to the RUC-recommended physician time. The commenters also believed that we have not appropriately accounted for the CPT Editorial Panel's revised additional physician work that is now inclusive in the code descriptor and increased intensity.

Response: We disagree with the commenter. For CPT code 19370, survey times showed only a slight increase in total time and slight decrease in intraservice time. Therefore, we continue to believe that the survey time does not support increasing the work RVU; in particular, there was no significant change in total time.

Comment: Commenters disagreed with the proposed work RVU of 9.98 for CPT code 19371 (*Peri-implant capsulectomy, breast, complete, including removal of all intra-capsular contents*) and stated that CMS should finalize the RUC-recommended work RVU of 10.81. Commenters also disagreed with the proposed work RVU of 11.17 for CPT code 1980 (*Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)*) and stated that we should finalize the RUC-recommended work RVU of 12.00. Commenters stated that they do not support the use of an incremental methodology as an appropriate method for identifying work RVUs for these PFS services. In particular, commenters noted that they believe this methodology adds fragility to the relative value system, as an error in the foundation code could affect the entire code family.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. For additional information regarding our use of an incremental difference for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: For CPT codes 19370, CPT code 19371, and CPT code 19380, commenters disagreed with our use of the chosen supporting reference codes throughout the code family stating they were not strong reference codes, and not relevant for purposes of valuation because there is no evidence of clinical comparison. A commenter also stated that the reference code used for CPT code 19380 had very low volume.

Response: We are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. Additionally, we use other methods to validate work RVUs, such as reference codes. When using referencing codes to support a proposed work RVU, we do not consider there to be a direct ''cross-walk'' between the CPT code that is being revalued and the chosen reference code. Instead, it is meant to be supportive in validating work times. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparisons to one another. We do not agree that codes must share the same patient population or utilization level to serve as an appropriate reference code. We also recognize that it is important to use recent available data regarding work times. However, we believe that while some reference code values may be considered older, they still provide support for revision of work RVUs when survey times show a marked increase or decrease in total and intraservice time, such as was the case for this code family.

After consideration of public comments, we are finalizing the work RVU and direct PE inputs for the

Secondary Breast Mound Procedure code family as proposed.

(8) Hip-Knee Arthroplasty (CPT Codes 27130 and 27447)

CPT codes 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*) and 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) were identified as potentially misvalued codes under the CMS high expenditure procedural code screen in the CY 2014 PFS final rule with comment period (78 FR 74334). These codes were reviewed by the AMA RUC who provided recommendations for work RVUs and physician time for these services for CY 2014. We agreed with the RUC recommendation to value CPT code 27130 and CPT code 27447 equally and thus established the same CY 2014 interim final work RVUs for these two procedures (78 FR 74334). This change resulted in a 1.12 work RVU increase for the visits in the global period. We added the additional work to the AMA RUC-recommended work RVU of 19.60 for CPT codes 27130 and 27447, resulting in an interim final work RVU of 20.72 for both services.

In the CY 2015 PFS final rule with comment period (79 FR 67632), we discussed how in the CY 2014 PFS final rule with comment period, we sought public comment regarding the appropriate work RVUs for these services and the most appropriate reconciliation for the conflicting information regarding time values for these services as presented to us by the physician community. We did not find the rationales provided for modifying the interim final work values established in CY 2014 compelling, and thus we finalized the CY 2014 interim final values for these procedures based upon the best data we had available and to preserve appropriate relativity with other codes.

In the CY 2019 PFS final rule (83 FR 59500 through 595303), CPT code 27130 and CPT code 27447 were added to the list of potentially misvalued codes. A stakeholder submitted information requesting that CMS nominate these codes as potentially misvalued. The stakeholder stated that there were substantial overestimates in pre-service and post-service time including follow-up inpatient and outpatient visits that do not take place included in the valuation of the service. As a result, the codes were resurveyed for the October 2019 RUC meeting.

We proposed the RUC-recommended work RVU of 19.60 for CPT code 27130 and the RUC-recommended work RVU of 19.60 for CPT code 27447. We also proposed the RUC-recommended direct PE inputs for both codes. Additionally, we solicited comment from the medical community on how to consider and/or include pre-optimization time (pre-service work and/or activities to improve surgical outcomes) going forward. We also noted that we were interested in stakeholders' thoughts on what codes could be used to capture these pre-optimization activities that could be billed in conjunction with the services discussed previously. Overall, we noted interest in continuing our ongoing dialog with stakeholders about how CMS might pay more accurately for improved clinical outcomes that may result from increased efficiency in furnishing care through activities, such as pre-optimization and are appreciative of information provided by the medical community. We invited the medical community to continue to engage with CMS on this and other topics.

We received public comments on Hip-Knee Arthroplasty (CPT codes 27130 and 27447). The following is a summary of the comments we received and our responses.

Comment: Many commenters were overall opposed to the proposal to reduce the work RVUs associated with CPT codes 27447 and 27130. Commenters noted that pre-optimization time is not captured in the current RUC survey. Commenters requested that CMS forgo any changes or delay adoption of the reduced work RVU for these procedures until an accurate assessment of this time can be determined. The commenters noted that delaying the adoption of these RVUs would provide time for CMS to work with stakeholders to better capture pre-optimization work performed by physicians to improve surgical outcomes. One commenter recommended the creation of a G code to account for arthroplasty pre-optimization work.

Two commenters appreciated CMS' interest in capturing these pre-optimization activities and seeking comment from the medical community on how to consider and/or include pre-optimization time going forward. Some stakeholders articulated that CMS may not have fully accounted for the preoperative work required to make value-based care cost-effective and high-quality. Commenters note, in light of the pandemic, that any cuts in payment to health care providers or medically necessary services would be harmful, and a reduction in work RVU is not justified by a reduction in time spent on patients, but will undercut the transition to bundled models.

One commenter was in support of CMS accepting the RUC recommendation for hip and knee arthroplasty and believes accepting the RUC recommendation will address the reimbursement imbalance, increase the primary care workforce, and improve the finances in primary care. Another commenter opposed the reduction because, if both the CF and RVU changes take effect, it would be a 15 percent reduction for physician payment. The commenter noted the RUC methodology does not capture the patient pre-optimization work related to the APM incentive that improves patient outcomes and lowers costs.

One commenter noted that patients with a higher BMI are more complex and the RVU should go up or a separate category be made for complicated joint replacement for those with a Body Mass Index (BMI) over 40. Additionally, the commenter noted that implants (for these procedures) should be reimbursed to facilities at cost or cost plus 10 percent, which would save millions of dollars per calendar year; and the commenter also believed lowering the RVUs may cause physicians to stop taking Medicare and reduce access to care.

One commenter noted overwhelming evidence that physicians and/or QHPs are spending more time with the typical patient in pre-service optimization work and stated that they believe CMS has broad authority to remedy the issues presented by the RUC recommendations for preservice time. Another commenter stated that there was logical outgrowth to add preservice time to the existing code.

One commenter noted that there are issues with the existing CPT codes in capturing arthroplasty pre-optimization activities or changes in practice patterns, and that creation of a new G code would account for arthroplasty pre-optimization work. For these procedures, this time includes patient screening and education, as well as coordinating with other health care providers to help manage the entire episode of care.

Response: We appreciate the commenters' feedback about maintaining the work RVU and potential resource costs that are not reflected in the RUC recommendation. We are also appreciative of the dialog we have had with stakeholders. We continue to assess the accuracy of service valuations, including global services paid under the PFS, and believe it would be prudent before considering

further changes to better understand how existing codes that could be billed prior to these procedures do not reflect the pre-optimization activities as described by stakeholders.

After considering the comments received, we are finalizing the RUC-recommended work RVU of 19.60 for CPT code 27130 and the RUC-recommended work RVU of 19.60 for CPT code 27447. We are also finalizing the RUC-recommended direct PE inputs for both codes. As we continue to consider this issue and how to best reflect pre-optimization in the valuation for the services, we welcome information from stakeholders as to which services may be included or which coding selections would be appropriate for various services that are or would be provided outside of the global period. We continue to be interested in stakeholders' thoughts and would like to discuss and consider the potential for more accurate coding, and what kind of coding framework, if there is currently none, could be used to capture these pre-optimization activities.

(9) Toe Amputation (CPT Codes 28820 and 28825)

These services were identified by the RUC Relativity Assessment Workgroup through a site of service anomaly screen based on the review of 3 years of data (2015, 2016 and 2017) for services with utilization over 10,000 in which a service is typically performed in the inpatient hospital setting, yet only a half discharge day management identified by CPT code 99238 is included. Prior to conducting the RUC survey, the specialty societies recommended that it would be appropriate for these services to have their global period changed from 090-day to 000-day so the site of service is less of a contributing factor to the codes' valuation. These codes were surveyed as a 000-day global service, and we proposed them as 000-day global services.

We disagreed with the RUC-recommended work RVU of 4.10 for CPT code 28820 (*Amputation, toe; metatarsophalangeal joint*). We noted that we believe that it would be more accurate to propose a work RVU of 3.51, and we are supporting this value with a crosswalk to CPT code 33958 (*Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed*)), which has a work RVU of 3.51, to account for the decrease in the surveyed work time. We do not believe the RUC-recommended reduction in work RVU from the current value of 5.82 is commensurate with the RUC-recommended 102-minute reduction in total time. We believe that a further reduction in work RVUs is warranted given the significant reduction in RUC-recommended physician time.

We disagreed with the RUC-recommended work RVU of 4.00 for CPT code 28825 (*Amputation, toe; interphalangeal joint*). We proposed a work RVU of 3.41 based on the RUC-recommended increment relationship between this code and CPT code 28820 (a difference of −0.10), which we apply to our proposed value for the latter code. We noted that we do not believe the RUC-recommended reduction in work RVU from the current value of 5.37 is commensurate with the RUC-recommended 97-minute reduction in total time. We also noted that we believe that a further reduction in work RVUs is warranted given the significance of RUC-recommended reduction in physician time.

For the direct PE inputs, we proposed to refine the pre-service clinical labor times to conform to the 000-day global period standards for both codes in the family for CPT codes 28820 and 28825. We also proposed to refine the clinical labor times for the ''Provide education/obtain consent'' (CA011) and the ''Prepare room, equipment and supplies'' (CA013) activities to conform to our established standard time of 2 minutes each in the non-facility setting for CPT codes 28820 and 28825. We proposed to refine the equipment time to conform to these changes in the clinical labor time for both codes.

We received public comments on the Toe Amputation (CPT codes 28820 and 28825).The following is a summary of the comments we received and our responses.

Comment: Commenters stated that CMS made this proposal without demonstrating that the agency also considered the disparity between the physician work intensity of the post-operative services that were previously bundled in 28820 and the physician work intensity of the skin-to-skin time of the service.

Response: We disagree with the commenter that we did not consider the disparity in intensity between the post-operative services that were previously bundled in CPT code 28820 and the skin-to-skin time of the service. Consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. This includes changes in the resource of time associated with the post-operative services that were previously bundled in CPT code 28820. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. In the case of CPT codes 28220 and 28222, we believe that in many cases the work time was reduced substantially but the work RVU only minimally, which resulted in an implied increase in the intensity of work that does not appear to be valid, and ultimately creates work intensity anomalies.

Comment: Commenters stated that the crosswalk code that CMS used to support its proposal to reject the RUC recommendation, CPT code 33958, is not an appropriate reference code to use for making valuation decisions. The commenter stated that CPT code 33958 is an atypical 000-day global code that includes a bundled inpatient hospital visit making it inappropriate to use as a direct work value crosswalk for a service that does not include bundled visits and it is a low volume service.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: One commenter stated that they would also like to remind CMS of both the Agency's and the RUC's longstanding position that treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and that inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation.

Response: We reiterate our previous clarification that we do not treat all components of physician time as having

identical intensity. As we have consistently stated, when our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs.

Comment: Commenters stated that it does not appear that CMS considered the change in the global surgical period from a 90-day global to a 000-day global when referencing the decrease in total time for the procedure, which would make sense for a change in the global period and the associated intensity for the procedure. The intra-service time for the procedure did not change.

Response: We noted that in reviewing the recommended values for CPT codes 28820 and 28825, the change in global periods was taken into consideration. However, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. This includes changes in the resource of time associated with the post-operative services that were previously bundled in CPT code 28820.

Comment: Several commenters stated that CMS should not impose the standard 000-day clinical labor times for CA011 and CA013 with respect to CPT codes 28820 and 28825 without regard to the clinically significant information that these are major procedures that are typically performed in a facility setting.

Response: We have reviewed all the information provided by commenters and we believe it would be appropriate to maintain standard times for particular clinical labor tasks that can be applied consistently to many codes, as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards provides greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. Therefore, we maintain that these refinements are consistent with the clinical labor times of a 000-day global service.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the Toe Amputation codes as proposed.

(10) Shoulder Debridement (CPT Codes 29822 and 29823)

In September 2019, the CPT Editorial Panel approved revision of CPT code 29822 (*Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]*)) and CPT code 29823 (*Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]*)) to clarify limited and extensive debridement by specifying the number of discrete structures debrided and providing examples of the structures.

We proposed the RUC-recommended work RVU of 7.03 for CPT code 29822 and 7.98 for CPT code 29823 without refinement.

For the direct PE inputs, we proposed the RUC recommendations CPT codes 29822 and 29823 without refinement.

We did not receive public comments on this code family, and are finalizing as proposed.

(11) Absorbable Nasal Implant Repair (CPT Codes 30468)

In September 2019, the CPT Editorial Panel approved the addition of CPT code 30468 (*Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)) to report repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s*)).

We proposed the RUC-recommended value of 2.80 work RVUs without refinement for CPT code 30468.

For the direct PE inputs, we also proposed the RUC-recommended values without refinement.

We received public comments on the Absorbable Nasal Implant Repair family (CPT code 30468). The following is a summary of the comments we received and our responses.

Comment: Several commenters stated their support for our proposal to adopt the RUC-recommended values without refinement.

Response: We thank commenters for their feedback and support.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for CPT code 30468 as proposed.

(12) Lung Biopsy-CT Guidance Bundle (CPT Code 32408)

CPT codes 32405 (*Biopsy, lung or mediastinum, percutaneous needle*) and 77012 (*Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation*) were identified by the AMA through a screen of code pairs that are reported on the same day, same patient and same NPI number at or more than 75 percent of the time. The CPT Editorial Panel deleted CPT code 32405 and replaced it with 32408 (*Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed*).

We did not propose the RUC-recommended work RVU of 4.00, which is the survey median, because we believe this value somewhat overstates the increase in intensity. Although we do not imply that the decrease in time, when considering the aggregate time values for CPT codes 32405 and 77012, as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in the work RVU. Intraservice and total time ratios using the aggregate time values of current CPT codes 32405 and 77012 suggest a significantly lower work RVU; however, we did not believe a decrease from the current aggregate value of 32405 and 77012 was warranted. We noted that we believe there is some overlap in physician work and time for the two current services, and that the recommended increase to 4.00 does not appropriately recognize this overlap. Therefore, we proposed a work RVU of 3.18, which is the sum of the work RVUs of the two base codes.

We proposed the RUC-recommended direct PE inputs without refinement.

We received public comments on Lung Biopsy-CT Guidance Bundle (CPT code 32408). The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with our valuation methodology, stating that it inappropriately relies on time-based ratios. The commenter stated this methodology is flawed and inaccurately treats all components of the physician time as having identical intensity and is incorrect. In addition, the commenter suggested it lacks the rigor of the survey

process and RUC panel evaluation. The commenter stated that CMS does not provide any supporting rationale or clinical information for the proposed work RVU of 3.18 other than debating survey times, primarily the intraservice time and total time ratios for this service, then justifying the proposed work RVU with the work RVU sum of deleted code 32405 and imaging code 77012.

The commenter also states that CMS overlooked the compelling evidence rationale for why this service is presently misvalued, and that cancer treatment protocols have evolved significantly to require more definitive tissue diagnosis including biomolecular marker profiles. The new code 32408 has increased the total time and the intensity/complexity, warranting the RUC-recommended work RVU of 4.00

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. Please see above for our discussion of compelling evidence rationale. We do consider changes in technology, patient population, etc., insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation framework stipulated by statute. In addition, we reiterate that our proposal for this code was based on our analysis which indicated that there is some overlap in the work described in the two base services CPT codes 32405 and 77012. We continue to believe that a work RVU that is in excess of the aggregate work RVU of these two codes would result in an overestimation of intensity.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for CPT code 32408 as proposed.

(13) Atrial Septostomy (CPT Codes 33741, 33745, 33746)

Septostomy procedures are performed on extremely small newborns and neonates with severe forms of congenital heart disease and are lifesaving/temporizing procedures that do not provide definitive therapy to these critically ill patients. These procedures are not typical of the Medicare population and are of low volume. CPT code 92992 (*Atrial septectomy or septostomy; transvenous method, balloon (e.g., Rashkind type) (includes cardiac catheterization)*) and CPT code 92993 (*Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)*), are carrier-priced codes. These services were not formally designated as potentially misvalued in the CY 2019 PFS final rule (83 FR 59500), but we did make mention that the RUC had signaled its intention to review these two codes. Both services were referred to the CPT Editorial Panel by the specialty societies who indicated that CPT code 92992 may not have included related imaging guidance, and also commented that CPT code 92993 was antiquated and rarely performed. The CPT Editorial Panel deleted both CPT codes and proposed to replace them with the following new CPT codes.

CPT code 33741 (*Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (e.g., Rashkind, Sang-Park, balloon, cutting balloon, blade)*), is one of three codes intended to replace the two deleted Septostomy codes. For CPT code 33741, the RUC recommended an RVU only crosswalk to CPT code 33340 (*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation*), which has a work RVU of 14.00. The RUC recommended 20 minutes of preservice evaluation time, 15 minutes of preservice positioning time, 15 minutes preservice scrub/dress/wait time, 55 minutes intraservice time and 45 minutes immediate postservice time, for 150 minutes total time. We proposed the RUC-recommended work RVU of 14.00 and physician times without refinement.

CPT code 33745 (*Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt*) is another new procedure code proposed by the CPT Editorial Panel. The service is currently performed on neonate infants to children with severe forms of congenital heart disease, by having a stent implanted inside of an infant's beating heart (and not within a blood vessel). This stent replaces the methods described in the deleted atrial septostomy codes utilizing the balloon and blade method. The RUC recommended 25 minutes preservice evaluation time, 15 minutes preservice positioning time, 15 minutes preservice scrub/dress/wait time, 92 minutes intraservice time and 60 minutes immediate postservice time, for 207 minutes total time. The RUC recommended 20.00 work RVUs for CPT code 33745. We proposed to adopt the RUC-recommended work RVUs and physician times.

CPT code 33746, (*Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)*), is the add-on code to the proposed new procedure CPT code 33745, for 60 minutes of physician intraservice time. The RUC recommended a work RVU of 10.50 for CPT code 33746. This value for the add-on code, in comparison to the recommended work value of 20.00 RVUs with 92 minutes/intraservice time and 207 minutes of total time for CPT code 33745, appears to be unsupportable given the 60 minutes of additional physician intraservice time. We proposed a work RVU of 8.00 for add-on CPT code 33746, which is the 25th percentile value from the survey and of similar valuation from reference CPT code 93592 (*Percutaneous*

transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)).

This family of CPT codes are facility-only services and have no direct PE inputs.

We received public comments on the proposed values for the Atrial Septostomy CPT codes 33741, 33745, 33746. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of CMS proposing the work RVUs as recommended by the AMA RUC for CPT code 33741, at 14.00, and for CPT code 33745, at 20.00. Commenters disagreed with CMS proposing 8.00 work RVUs for CPT code 33746, that differs from the AMA RUC recommended value of 10.50. Commenters did not believe that the work RVU of 8.00 from CPT reference code 93592 (also an add-on code with the same amount of physician time), and from the survey's 25th-percentile work RVU value adequately reflected the resources involved in furnishing the service and suggested instead the survey's 50th-percentile median value of 10.50 RVUs due to the intensity of the work in CPT code 33746, which involves the typical patient who is a small child or infant. The commenters stated that add-on code 33746 is not intended as an extension of an initial stent procedure described by CPT code 33745 and that CPT code 33746 is the placement of a second stent where the work is more intense than the primary procedure, CPT code 33745.

Response: For the new proposed CPT codes 33741 and 33745, the AMA RUC-recommended work RVUs values are considered higher in relationship to the physician times to perform the procedures and they note that this higher relationship is due to these procedures' higher than typical work intensity. The surveyed work RVU for CPT code 33741 at the 25th-percentile was 10.99 but the AMA RUC-recommended value was 14.00, which was lower than the 50th-percentile median value of 17.00 RVUs and about midpoint between these upper and low quartiles. The surveyed work RVU at the 25th-percentile for CPT code 33745 was 20.00 which the AMA RUC recommended.

The surveyed work RVU for add-on code CPT code 33746 at the 25th-percentile was 8.00 but the AMA RUC recommended the work RVU of 10.50 from the 50th-percentile median value, based on rationale similar to the rationale discussed above. For CPT code 33746, on the measure of physician time alone for 60 minutes we see comparable add-on codes with the identical amounts of physician time, valued at much less than their recommended 10.50 work RVUs, and much less than the CMS' referenced CPT code 93592's 8.00 work RVUs. Seeing that AMA RUC surveyed work RVU at the 25th percentile yielded a value of 8.00 and that our comparator CPT code 93592 is also valued at 8.00 for 60 minutes of physician time, we continue to believe that 8.00 work RVUs is the correct value for CPT code 33746.

After consideration of the comments, we are finalizing the work RVU for CPT code 33741, CPT code 33745, and CPT code 33746, as proposed.

(14) Percutaneous Ventricular Assist Device Insertion (CPT Codes 33995, 33990, 33991, 33992, 33997, and 33993)

In May 2019, the CPT Editorial Panel approved the revision of four codes to clarify the insertion and removal of right and left heart percutaneous ventricular assist devices (PVAD), and the addition of two codes to report insertion of PVAD venous access and removal of right heart PVAD. These codes were surveyed with 000-day global periods and reviewed at the October 2019 RUC meeting.

We proposed the RUC-recommended work RVUs for all six codes in the family. We proposed a work RVU of 6.75 for CPT code 33990 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only*), a work RVU of 6.75 for CPT code 33995 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only*), a work RVU of 8.84 for CPT code 33991 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture*), a work RVU of 3.55 for CPT code 33992 (*Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), separate and distinct session from insertion*), a work RVU of 3.00 for CPT code 33997 (*Removal of percutaneous right heart ventricular assist device, venous cannula, separate and distinct session from insertion*), and a work RVU of 3.10 for CPT code 33993 (*Repositioning of percutaneous right or left heart ventricular assist device, with imaging guidance, at separate and distinct session from insertion*).

Stakeholders contacted CMS regarding the valuation of the codes in this family following the arrival of the RUC recommendations. They stated that the RUC recommendations did not accurately reflect the work time of these procedures, which they stated to be increasing due to the adoption of new technology. The stakeholders requested that CMS propose to maintain the current work RVUs for the codes in this family and to crosswalk the work RVU of the new codes to existing codes.

We disagreed with the stakeholders and proposed the RUC-recommended work RVUs for each code in this family as noted previously. We noted that in this case where the surveyed work times for the existing codes are decreasing and the utilization of CPT code 33990 is increasing significantly (quadrupling in the last 5 years), we have reason to believe that practitioners are becoming more efficient at performing the procedure, which, under the resource-based nature of the RVU system, lends support for proposing the RUC's recommended work RVUs. Although the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We disagreed with the stakeholders that the incorporation of this new technology would necessarily be grounds for maintaining the current work RVU, as improvements in technology are commonplace across many different services and are not specific to this procedure. As detailed earlier, we also have reason to believe that the improved technology has led to greater efficiencies in the procedure which, under the resource-based nature of the RVU system, lends further support for proposing a lower work RVU for the existing CPT codes.

The RUC did not recommend and we did not propose any direct PE inputs for this facility only code family. We proposed a 000-day global period for all six codes as surveyed by the RUC.

We received public comments on the codes in the Percutaneous Ventricular Assist Device Insertion family. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the CMS decision to propose the RUC-recommended work RVUs for each code in the family and recommended that CMS finalize the proposal.

Response: We appreciate the commenters' support for our proposals.

Comment: A commenter stated that the RUC recommendations included in the PFS proposed rule did not accurately reflect the full work associated with percutaneous ventricular assist device (PVAD) procedures. The commenter stated that

the RUC recommendations do not reflect increases in intra-procedure time resulting from the increased usage of SmartAssist technology and that if work value reductions continue over multiple years, it will impede physician adoption of these new technologies, resulting in a negative impact on patient access.

Response: We appreciate the information provided by the commenter and we share in their concerns regarding the need to maintain patient access to these services. However, as we stated in the proposed rule, we have reason to believe that practitioners are becoming more efficient at performing the procedures, which, under the resource-based nature of the RVU system, gives support for proposing the RUC's recommended work RVUs. We disagree with the commenter that the incorporation of this new technology would necessarily be grounds for maintaining the current work RVU, as improvements in technology are commonplace across many different services and are not specific to this procedure. We continue to believe that the RUC-recommended work RVUs are the most accurate valuations for the codes in this family.

After consideration of the public comments, we are finalizing our proposed work RVUs for the codes in the Percutaneous Ventricular Assist Device Insertion family. We did not propose and we are not finalizing any direct PE inputs for this facility only code family.

(15) Esophagogastroduodenoscopy (EGD) With Biopsy (CPT Code 43239)

In the CY 2019 PFS final rule (83 FR 59500), CPT code 43239 (*Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple*) was publicly nominated for review under the potentially misvalued code initiative. As requested, the specialty societies conducted a survey for the April 2019 RUC meeting. The RUC survey results showed that the current work RVU of 2.39, which is below the survey 25th percentile work RVU of 2.50, accurately reflects the physician work for CPT code 43239.

We proposed to maintain the current work RVU of 2.39 as recommended by the RUC. We proposed the RUC-recommended direct PE inputs for CPT code 43239 without refinement.

We received public comments on Esophagogastroduodenoscopy (EGD) with Biopsy (CPT code 43239). The following is a summary of the comments we received and our responses.

Comment: The commenters all agreed with the CMS proposal to maintain the current work RVU of 2.39 as recommended by the RUC. The commenters also all agreed with the CMS proposal of the RUC-recommended direct PE inputs with without refinement.

Response: We appreciate the commenters' support for CMS proposing the RUC recommendation for CPT code 43239.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 2.39 for CPT code 43239. We are also finalizing the RUC-recommended direct PE inputs for CPT code 43239 without refinement.

(16) Colonoscopy (CPT Code 45385)

In the CY 2019 PFS final rule (83 FR 59500), CPT code 45385 (*Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique*) was publicly nominated for review under the potentially misvalued code initiative. As requested, the specialty societies conducted a survey for the April 2019 RUC meeting. The RUC survey results showed that the current work RVU of 4.57, which is slightly above the survey 25th percentile work RVU of 4.50, accurately reflects the physician work for CPT code 45385.

We proposed to maintain the current work RVU of 4.57 as recommended by the RUC. We proposed the RUC-recommended direct PE inputs for CPT code 45385 without refinement.

We received public comments on Colonoscopy (CPT code 45385). The following is a summary of the comments we received and our responses.

Comment: The commenters all agreed with the CMS proposal to maintain the current work RVU of 4.57 as recommended by the RUC. The commenters also all agreed with the CMS proposal of the RUC-recommended direct PE inputs with without refinement.

Response: We appreciate the commenters' support for our proposal to adopt the RUC recommendation for CPT code 45385.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 4.57 for CPT code 45385. We are also finalizing the RUC-recommended direct PE inputs for CPT code 45385 without refinement.

(17) Transrectal High Intensity Focused US Prostate Ablation (CPT Codes 55880)

In May 2019, the CPT Editorial Panel established a new code to report ablation of malignant prostate tissue with high intensity focused ultrasound (HIFU), including ultrasound guidance. For CPT code 55880, we did not propose the RUC recommendation to use the survey median work RVU of 20.00 to value this service because we believe total time ratios to the two key reference codes, CPT codes 55840 (*Prostatectomy, retropubic radical, with or without nerve sparing*) and 55873 (*Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)*) indicate that this value is somewhat overstated and does not accurately reflect the physician time, and because an analysis of all 090-global period codes with similar time values indicates that this service is overvalued.

We proposed a work RVU of 17.73 based on a crosswalk to CPT code 69930 (*Cochlear device implantation, with or without mastoidectomy*) which has similar total time and identical intraservice time values and is more consistent with other codes of similar time. We proposed the RUC-recommended PE inputs without refinement.

We received public comments on Transrectal High Intensity Focused US Prostate Ablation (CPT code 55880). The following is a summary of the comments we received and our responses.

Comment: Commenters noted that, for CPT code 55880, the RUC recommended the survey 25th percentile work RVU of 20.00, not the survey median work RVU, as it is misstated in the proposed rule.

Response: We regret the error, and we note that the RUC indeed recommended the survey 25th percentile work RVU.

Comment: In response to this section, the RUC commented that they are increasingly concerned that CMS is eschewing the bedrock principles of valuation within the RBRVS (namely, magnitude estimation, survey data and clinical expertise) in favor of arbitrary mathematical formulas and, in their opinion, making distinctions in the different types of physician time, which are ''CMS/Other'' time source, ''Harvard'' time source, and ''RUC'' time source (from physician surveys). The RUC suggested CMS use valid survey data and review the actual relativity for all elements (physician work, time, intensity and complexity) when developing work values for services and not foster flawed methodologies.

Response: As we have discussed in previous rules, we agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when physician times are measured, significant discrepancies can occur. However, we also continue to believe that our operating assumption regarding the validity of the existing time values as a point of comparison is critical to the integrity of the current relative value system. The physician times and intensities currently

associated with codes play important roles in PFS ratesetting in their comparativeness to each other, in establishing work RVUs. The PFS is grounded in and reliant on the original relativity of the RBRVS, and then as services, codes and values evolve over the years, the PFS statute contemplates maintaining and building on that base-level of relativity. If we were to question the assumption that previously recommended work times had routinely been over- or underestimated, this would undermine the basis for relativity of the work RVUs on the PFS. Given that the process under which codes are often valued by comparison to codes with similar times, we acknowledge the distinction between ''CMS/Other'' times, ''Harvard'' times, and ''RUC'' physician surveyed times, but we do not believe we can apply different validation weights to any of these sources of time values while remaining consistent with our obligation to consider time and intensity as these are currently reflected in the fee schedule. They are all physician time data collected over many years. We understand that some time values may not have been reviewed or re-surveyed in a number of years, but that alone is not an indicator of the current relative accuracy of a time value.

We believe that, over the years as more codes are being reviewed and examined, the entire collective fee schedule of procedure codes should align in a very reliable and accurate relative value system reflecting each code's relativity with respect to other codes (in their work RVUs, in their procedure times, and in their work intensities). We recognize that adjusting work RVUs for changes in physician times is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we always try to apply various methodologies to identify several potential work values for individual codes before deciding on the one we find most appropriate. Our review of code values under the PFS not only examines the relationships between work, time, and intensity, but we also look at magnitude and rank order anomalies, particularly in families or groups of codes that are closely related but may differ slightly in degrees found in their clinical descriptions and possibly in the typical beneficiary populations that each code might serve. Among these codes, we try to maintain the accurate relative relationships in terms of time, work, and intensity measurements. In some cases, where there are marked improvements in medical techniques and technologies, we may find efficiencies in physician's work for certain services that warrant decreases in physician's times, but we also recognize that some improvements may introduce greater complexity and either an increase in intensity and/or in physician times. We reiterate that we believe it would be irresponsible to ignore or discount ''CMS/Other'' times or ''Harvard'' times in our data system, and that we need to consider all times and all intensities and all clinically relevant relatedness (or non-relatedness) of procedure codes to each other in establishing more refined work RVUs for PFS services. Also note that physician times considered to be ''RUC'' physician times as they are listed in the RUC database are not always necessarily AMA RUC surveyed times. We may have adjusted AMA RUC surveyed times in our annual review of all HCPCS codes; and the same can be said of times that the AMA labels as ''Harvard'' or ''CMS/Other'' physician times.

Comment: Many commenters stated that the proposed work RVU was too low to adequately reflect the work, skill and complexity required for this procedure. Commenters were concerned about patient access, stating that a significant number of Medicare beneficiaries with prostate cancer will not have access to this procedure. Commenters encouraged CMS to finalize the RUC-recommended work RVU of 20.00. Commenters stated that CMS did not provide any supporting rationale or clinical information for the proposed work RVU of 17.73 other than debating survey times, primarily the total time ratios between a service that is not currently covered to the two key reference codes, then justifying our proposed work RVU with a crosswalk to CPT code 69930. Commenters stated that this crosswalk is flawed in that it was surveyed 12 years ago, and it is clinically a very different procedure. A commenter suggested CPT code 42420 (*Excision of the parotid tumor or parotid gland*) with a work RVU of 19.53 as a more appropriate crosswalk as it is a more intense procedure than our proposed crosswalk CPT code 69930.

Response: Our proposed work RVU of 17.73 is not solely derived from time ratios. Our analysis included comparisons to other codes of similar time values as well as to codes with similar numbers of the total number of post-op visits, as well as a consideration of the RUC-recommended key reference services. These factors all indicated a work RVU lower than the recommended 20.00. Comparison of relative intensity values further indicates this RVU is somewhat overvalued. Our proposed value of 17.73 produces an intensity value of 0.066, which is very similar to the intensity value for our crosswalk CPT code 69930, which is 0.067. We disagree that the patient populations of these two codes are too different; the description and vignettes of CPT code 69930 do not indicate that this is primarily a pediatric procedure. Further, we reiterate that, although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. We continue to believe the time values and relative intensity of this procedure indicate that a work RVU of 17.73 is a more accurate valuation, and we are finalizing this work RVU as proposed.

After consideration of the public comments, we are finalizing as proposed a work RVU of 17.73, as well as the RUC-recommended direct PE inputs without refinement.

(18) Computer-Aided Mapping of Cervix Uteri (CPT Code 57465)

In September 2019, the addition of CPT code 57465 (*Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (List separately in addition to code for primary procedure)*) was approved by the CPT Editorial Panel to report computer-aided mapping of cervix uteri during colposcopy. The RUC recommended the survey median work RVU of 0.81 for this service.

We proposed the RUC-recommended value of 0.81 for CPT code 57465. We also proposed the RUC-recommended direct PE inputs for this code.

We solicited comment on a new medical supply indicated on the PE spreadsheet submitted by the RUC. A ''computer aided spectral imaging system (colposcopy) disposal speculum'' was noted in the RUC PE meeting materials. This name suggests it is digital. However, on the actual invoice submitted, the supply item in question was listed as a ''disposable medium speculum'' with no mention of a spectral imaging system or a digital component. We researched this speculum and could not find any evidence that it has a digital component. Therefore, we proposed to change the name of this new supply item to ''disposable speculum, medium'' (SD337) to reflect the actual product on the invoice submitted. We sought clarification as to what aspect of the

speculum is digital or if a cheaper, non-digital speculum would suffice. We noted for example that the vaginal specula (SD118) supply has a CY 2021 price of $1.12 and we were able to find disposable medium specula readily available online for a price of roughly $1.00. We proposed the new SD337 supply at the $5.80 price as listed on the invoice submitted in the RUC materials and sought comment as to why other disposable speculums at a lower price would not be typical for this procedure.

We received public comments on the Computer-Aided Mapping of Cervix Uteri code family (CPT code 57465). The following is a summary of the comments we received and our responses.

Comment: Commenters were overall in support and appreciated CMS proposing the RUC-recommended work RVU and the direct PE inputs for code 57465. We also received comments with additional information on the SD337 supply item in question. Commenters stated that in order for the map to be successfully generated, there are stringent technical requirements of the vaginal speculum that require it to be attached to the optical head of the system. Commenters stated that the specula are therefore custom designed to meet performance standards, and are an integral part of the imaging system. One commenter noted that the speculum referenced is typical. The coating on the plastic that enhances the image is necessary, and without its light reflection on plastic interferes with the image processing.

Response: We appreciate the additional information provided from commenters and the commenters' agreement with the proposed name change and that the item referenced is typical for the service noted.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 0.81 for CPT code 57465. We are also finalizing the proposed RUC-recommended direct PE inputs for this code. We are finalizing the new SD337 supply at the $5.80 price as listed on the invoice submitted in the RUC materials based on the public comments submitted. To clarify the nature of the supply, we are renaming SD337 to ''digital imaging speculum'' to reflect what the commenters stated would be more accurate.

(19) Colpopexy (CPT Codes 57282 and 57283)

The CPT codes 57282 (*Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)*) and 57283 (*Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)*) were identified by the RUC Relativity Assessment Workgroup as services performed less than 50 percent of the time in the inpatient setting yet include inpatient hospital E/M services within the global period and the 2018 Medicare utilization is over 5,000. This code family was surveyed and reviewed for the January 2020 RUC meeting. For CY 2021, the RUC recommended a work RVU of 13.48 for CPT code 57282, and a work RVU of 13.51 for CPT code 57283.

We disagreed with the RUC-recommended work RVUs for the CPT code family of 57282 and 57283. We proposed a work RVU of 11.63 for CPT code 57282, and also proposed to maintain the current work RVU of 11.66 for CPT code 57283. For CPT code 57283, we based our disagreement on the total time ratio between the current time of 349 minutes and the recommended time established by the survey of 231 minutes. This ratio equals 66 percent, and 66 percent of the current work RVU of 11.66 for CPT code 57283 equals a work RVU of 7.70. When we reviewed CPT code 57283, we found that the recommended work RVU was higher than other codes with similar time values. This is supported by the reference CPT codes we compared to CPT code 57283 with 90 minutes of intraservice time; reference CPT code 19350 (*Nipple/areola reconstruction*) has a work RVU of 9.11 with 229 minutes of total time, and reference CPT code 47563 (*Laparoscopy, surgical; cholecystectomy with cholangiography*) which has a work RVU of 11.47 with 238 minutes of total time. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we noted that we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. The recommendation from the RUC acknowledged that the time had decreased for CPT code 57283, and also noted that there has been an increase in intensity due to a change in technique and knowledge necessary to perform the service. In the case of CPT code 57283, we noted that we believe it would be more accurate to propose maintaining the current work RVU of 11.66 instead of the RUC-recommended work RVU of 13.51 to account for these decreases in the surveyed work time while still accounting for the increase in intensity. We also noted that the intensity of CPT code 57283 would nearly double by maintaining the proposed work RVU of 11.66, due to the significant decreases in surveyed work time, which we believe supported the RUC's contention that the intensity of this code has increased over time.

For CPT code 57282, we disagreed with the RUC-recommended RVU of 13.48. We noted that the significant decrease in total time for code 57282 suggests an RVU lower than 13.48. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 57282 and 57283 is equivalent to the RUC-recommended interval of 0.03 RVUs. We noted that we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Therefore, we proposed a work RVU of 11.63 for CPT code 57282, based on the RUC-recommended interval of 0.03 RVUs below our proposed work RVU of 11.66 for CPT code 57283.

We proposed the RUC-recommended direct PE inputs for the CPT code family of 57282 and 57283 without refinement.

We received public comments on the Colpopexy code family (CPT codes 57282 and 57283). The following is a summary of the comments we received and our responses.

Comment: The commenters disagreed with our proposal to value CPT code 57282 using an incremental methodology, and stated that the proposal inaccurately treats all components of the physician time as having identical intensity. The commenters would prefer that CMS finalize the RUC-recommended value rather than values derived by increments. Moreover, commenters stated that CMS proposed the RUC work RVU increment (0.03) between CPT codes 57282 and 57283 for this code family, yet disagreed with the RUC-recommended work RVU.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We noted that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service.

Comment: Commenters stated that the RUC recommendation for CPT code 57282 was based on robust survey results and requested that CMS adopt the RUC-recommended work values. The commenters stated that the current work value and time for CPT code 57282 were derived from the Harvard studies, and therefore, are not resource based. Commenters stated that they could not support comparing the original Harvard value of this service, which is over 25 years old and whose source is unknown, to time and work derived from a recent survey. Commenters stated that CPT code 57282 has never been surveyed by the RUC and the IWPUT for the current times and work RVU (0.014) are inappropriately low for this intense major surgical procedure, not that much higher than the intensity for pre-service scrub/dress/wait time, which strongly implies the current total times are inflated relative to the current work RVU and not valid for comparison to the new times. Commenters stated that the increased intra-service time can be attributed to the support sutures being placed at multiple points of attachment, which was not done in the past. Commenters stated that the largest difference in the total time comes from the hospital visit time assigned by Harvard in 1992.

Response: We agree that it is important to use the recent data available regarding time, and we acknowledge that when many years have passed between when work time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important element in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been underestimated or overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times and it undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: We received several comments regarding the decrease in total times for CPT codes 57282 and 57283. For CPT code 57282, a few commenters stated that the largest difference in the total time comes from the hospital visit time assigned by Harvard in 1992, which makes CMS' rationale to recommend a lower work RVU based on the ''significant decrease in total time'' completely flawed and unjustified. For CPT code 57283, the commenters disagreed that the decreased total time should result in a lower work RVU than the RUC recommendation, and stated that although the current times for CPT code 57283 have decreased according to the RUC survey data, the overall intensity and complexity has increased significantly.

Response: For CPT codes 57282 and 57283, we disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services will be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Some comments stated that the proposed rule did not discuss the RUC's compelling evidence rationale for why CPT codes 57282 and 57283 are presently undervalued, suggesting that CMS missed considering this rationale. Commenters stated that there has been a change in the physician work necessary to perform these services based on a change in technique and knowledge of the problem. Commenters stated that there has been a change in technology due to functional MRI studies which have increased what is known about pelvic organ prolapse and what structures are important to successful repair. Some commenters went on to describe the extent of dissection required and the change in technique which is now standardized when performing CPT codes 57282 and 57283.

Response: We agree with the commenters that due to changes in technology for CPT codes 57282 and 57283 we had reason to believe that practitioners are becoming more efficient at performing these procedures. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We do not agree with the commenters that a change in the work pattern, and more dissections and greater use of sutures, would necessarily be grounds for increasing the work RVUs as recommended by the RUC, as improvements in technology are commonplace across many different services and are not specific to these procedures. We also have reason to

believe that the improved technology has led to greater efficiencies in these procedures which, under the resource-based nature of the RVU system, lends further support for the proposed work RVU of 11.63 for CPT code 57282 and 11.66 for CPT code 57283. Also, compelling evidence is not part of our statutory guidelines which require that the valuation of codes should be based on time and intensity. We do consider changes in technology, patient population, etc. insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation process stipulated by statute.

Comment: Several commenters stated that CMS is incorrect in proposing a work RVU of 11.66 for CPT code 57283 based on referencing codes 19350 and 47563. CPT code 19350, involves an incision made externally on the breast to dissect a small amount of tissue at the site where the nipple will be made. The surgical site is external to the body without proximate anatomical structures that would be affected by a subcutaneous incision. Also, CPT code 19350 can be performed under local anesthesia and is performed in the office setting 19 percent of the time. CPT code 47563 does not include the amount of dissection and tissue reattachment that CPT code 57283 does, and the radiographic work included in CPT code 47563 is not comparable to the intensity or risk of CPT code 57283.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate code comparison or an appropriate crosswalk.

Comment: Commenters appreciated that CMS proposed to accept the RUC-recommended direct PE inputs for CPT codes 57282 and 57283.

Response: We appreciated the commenters for their support.

After consideration of the public comments, we are finalizing the proposed work RVU of 11.63 for CPT code 57282 and the work RVU of 11.66 for CPT code 57283. We are also finalizing the RUC-recommended direct PE inputs for the codes in the Colpopexy family of codes (CPT codes 57282 and 57283) without refinement.

(20) Laparoscopic Colpopexy (CPT code 57425)

The CPT code 57425 (*Laparoscopy, surgical, colpopexy (suspension of vaginal apex)*) was identified by the RUC Relativity Assessment Workgroup as a service performed less than 50 percent of the time in the inpatient setting yet includes inpatient hospital E/M services within the global period and the 2018 Medicare utilization is over 5,000. This service was surveyed and reviewed for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 18.02 for CPT code 57425 and proposed to maintain the current RVU of 17.03 based on the total time ratio between the current time of 404 minutes and the recommended time established by the survey of 351 minutes. This was supported by the reference CPT codes we compared to CPT code 57425 with the same intraservice time; reference CPT code 26587 (*Reconstruction of polydactylous digit, soft tissue and bone*) which has a work RVU of 14.50, and reference CPT code 20696 (*Application of multiplane (pins or wires in more than 1 plane), unilateral, external fixation with stereotactic computer-assisted adjustment (e.g., spatial frame), including imaging; initial and subsequent alignment(s), assessment(s), and computation(s) of adjustment schedule(s)*) which has a work RVU of 17.56. Both CPT codes 26587 and 20696 have 180 minutes of intraservice time, which is equal to the 180 minutes of intraservice time in the RUC recommendation for CPT code 57425, and over 400 minutes of total time. The total time for CPT code 57425 decreased from 404 to 351 minutes and the RUC did not appear to take this into account. Therefore, we proposed to maintain the current work RVU of 17.03.

We proposed the RUC-recommended direct PE inputs for CPT code 57425 without refinement.

We received public comments on the Laparoscopic Colpopexy code family (CPT code 57425). The following is a summary of the comments we received and our responses.

Comment: The commenters disagreed that a decrease in total time for CPT code 57425 should result in a lower work RVU than the RUC recommendation since the intraservice time required to perform CPT code 57425 increased significantly. The commenters also stated that using a total time ratio approach in lieu of the RUC survey data for CPT code 57425 is erroneous.

Response: For CPT code 57425, we disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Commenters stated that CMS did not discuss the RUC's compelling evidence rationale in the proposed rule text for why CPT code 57425 is presently undervalued, and suggested CMS missed considering this rationale. The commenters further stated that the surgical techniques and technology for CPT code 57425 have changed drastically. Specifically, commenters stated that the technique has been refined and is now much more standardized than when CPT code 57425 was last surveyed in 2003. This decreased the complication rate and has changed the physician work. In addition, commenters stated that there is a change in technology due to functional MRI studies which have increased what is known about pelvic

organ prolapse and what is important for a successful repair. Some commenters stated that the dissection is difficult and requires more time, as shown in the RUC survey, for CPT code 57425.

Response: We agree with the commenters that due to a change in technology for CPT code 57425 we had reason to believe that practitioners are becoming more efficient at performing the procedure. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We do not agree with the commenters that a change in the work practice and new technology would necessarily be grounds for increasing the work RVU to 18.02 as recommended by the RUC, as improvements in technology are commonplace across many different services and are not specific to this procedure. We also have reason to believe that the improved technology has led to greater efficiencies in the procedure which, under the resource-based nature of the RVU system, lends further support for maintaining the current work RVU value of 17.03 for CPT code 57425 as proposed. Also, compelling evidence is not part of our statutory guidelines which require that the valuation of codes should be based on time and intensity. We do consider changes in technology, patient population, etc., insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation process stipulated by statute.

Comment: Some commenters stated that CMS is incorrect in proposing the current work RVU of 17.03 for CPT code 57425 when referencing CPT codes 26587 and 20696 because both procedures are performed on an external part of the body. Commenters went on to describe how the difficulty performing CPT codes 26587 and 20696 is not as great as performing CPT code 57425. For CPT code 26587, the physician is removing an external amount of tissue that includes bone and could be considered a sixth toe or finger, and has little risk to other organs or permanent disability. Commenters stated that there are not any close major blood vessels or an entire nerve plexus that must be avoided with CPT code 26587, while CPT code 57425 involves the placement of a synthetic mesh which must be performed properly to avoid erosion into a viscus, causing permanent long-term harm and multiple follow up surgeries. In addition, commenters stated that CPT code 26587 is a low volume Medicare procedure and was last reviewed by the RUC in 2001. CPT code 20696 is fixating an external metal frame onto someone's leg, which involves less risk and more space and visualization to perform than CPT code 57425.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate code comparison or an appropriate crosswalk. We looked to CPT codes 26587 and 20696 as reference codes for comparison to CPT code 57425 based on their total time ratios. Few other supporting codes with similar intraservice time and total time were found. The current work RVU of 17.03 is closer to the higher end of the RVUs within this reference code bracket that uses 26587 on the low end, and 20696 on the high end.

Comment: Commenters supported the CMS proposal of the RUC-recommended direct PE inputs for CPT code 57425.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing maintaining the current work RVU of 17.03 as proposed for CPT code 57425. We are also finalizing the RUC-recommended direct PE inputs for the codes in the Laparoscopic Colpopexy family of codes (CPT code 57425) without refinement.

(21) Intravitreal Injection (CPT Code 67028)

CPT code 67028 (*Intravitreal injection of a pharmacologic agent*) was identified via the RUC's Relativity Assessment Workgroup as a code where the original valuation was based on a crosswalk code that had since been revalued. The RUC recommended that CPT code 67028 should be surveyed for the April 2019 RUC meeting. We proposed the RUC-recommended work RVU of 1.44 for CPT code 67028.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Clean room/equipment by clinical staff'' (CA024) activity from the RUC-recommended 5 minutes to 3 minutes for CPT code 67028, because 3 minutes is the standard time for this clinical labor activity code, and we disagree that there would typically be a need for 2 additional minutes for cleaning, sterilizing, and re-packaging a reusable eyelid speculum in a sterile package to prepare for its next case. Additionally, 3 minutes is the standard time for cleaning the room *and* cleaning the equipment; although we agreed that these cleaning tasks would take place, we do not believe that the removal of the same day E/M visit would result in the need for 2 additional minutes of cleaning time. We noted that we are proposed to maintain the current time for this clinical labor activity, which was previously finalized in the CY 2011 PFS final rule at the standard value of 3 minutes (75 FR 73353). We also proposed to refine the equipment times to match the change in clinical labor time.

We received public comments on CPT code 67028. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they agreed with the CMS proposal of the RUC-recommended work RVU of 1.44. However, the commenter disagreed with the proposal to refine the clinical labor time for the ''Clean room/equipment by clinical staff'' (CA024) activity from the RUC-recommended 5 minutes to 3 minutes. The commenter stated that the 5 minutes listed for time to clean the room/equipment was not increased because of the absence of a same day E/M visit; rather, it was increased to appropriately reflect the current time it takes to clean/disinfect the room and equipment. The commenter stated that the eyelid speculum is soaked in an antiseptic solution for a fixed period of time, then scrubbed, repackaged, and sterilized in an autoclave, and that an infection from an unsterile piece of equipment for this intraocular procedure can directly lead to endophthalmitis which is permanently blinding. The commenter also stated that they disagreed with the CMS refinement of the equipment time for the vaccine refrigerator (ED043) equipment since the medication must be logged into an inventory tracking system and it is now typical for each physician to hire a private temperature monitoring service that requires a recurring fee.

Response: We disagree with the commenter regarding the refinements to the direct PE inputs for CPT code 67028. As we stated in the proposed rule, 3 minutes is the standard time for cleaning the room as well as cleaning the equipment, not one or the other. Although we appreciate the additional information stating that this cleaning time is not associated with an E/M visit, we do not agree that 2 minutes of additional clinical time would be

typical for this procedure, especially given that CPT code 67028 currently allocates the standard 3 minutes of clinical labor time for cleaning activities. For the vaccine refrigerator (ED043) equipment, the refinement to the equipment time was made to conform to the refinement in clinical labor time associated with cleaning the room. We also note that any fees associated with a monitoring service for the refrigerator's temperature would be an indirect cost akin to office rent and therefore would not be included in the direct PE inputs.

After consideration of the public comments, we are finalizing our proposed work RVU of 1.44 and our proposed direct PE inputs for CPT code 67028.

(22) Dilation of Eustachian Tube (CPT Codes 69705 and 69706)

In September 2019, the CPT Editorial Panel created two new codes, CPT code 69705 (*Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral*) and CPT code 69706 (*Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral*) to describe the dilation of the eustachian tube via surgical nasopharyngoscopy, unilateral and bilateral. We proposed the RUC-recommended work RVUs of 3.00 and 4.27 for CPT codes 69705 and 69706, respectively. For the direct PE inputs, we proposed the RUC-recommended values without refinement.

We received public comments on the Dilation of Eustachian Tube (CPT codes 69705 and 69706). The following is a summary of the comments we received and our responses.

Comment: Several commenters stated their support for CMS proposing the RUC-recommended values without refinement.

Response: We thank commenters for their feedback and support.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Dilation of Eustachian Tube family as proposed.

(23) X-Ray of Eye (CPT Code 70030)

CPT code 70030 (*Radiologic examination, eye, for detection of foreign body*) was identified through an updated screen of CMS/Other source codes with Medicare utilization over 20,000. We proposed the RUC-recommended work RVU of 0.18 for this service. We proposed the RUC-recommended direct PE inputs without refinement.

We received public comments on the X-Ray of Eye family (CPT code 70030). The following is a summary of the comments we received and our responses.

Comment: A commenter appreciated CMS' acceptance of the RUC recommendation for this code.

Response: We appreciate the support for our proposals.

After consideration of the public comments, we are finalizing the proposed work RVU of 0.18 as well as the proposed direct PE inputs for CPT code 70030.

(24) CT Head-Brain (CPT Codes 70450, 70460, and 70470)

In the CY 2019 PFS final rule (83 FR 59500 through 59503), a stakeholder nominated CPT code 70450 (*Computed tomography, head or brain; without contrast material*) as potentially misvalued, citing GAO and MedPAC reports that suggest that work RVUs are overstated for procedures such as these, and the specialty society surveyed family codes 70460 (*Computed tomography, head or brain; with contrast material(s)*) and 70470 (*Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections*). We proposed the RUC recommendation to maintain the current work RVUs of 0.85, 1.13, and 1.27 for CPT codes 70450, 70460, and 70470, respectively. For CPT code 70450, we note that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70486 (*Computed tomography, maxillofacial area; without contrast material*), which has similar physician time and the same work RVU, is appropriate. For CPT code 70460, we noted that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70487 (*Computed tomography, maxillofacial area; with contrast material(s)*), which has similar physician time and the same work RVU is appropriate. Similarly, for CPT code 70470, we noted that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70488 (*Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections*), which has similar physician time and the same work RVU, is appropriate. We also noted that these codes are relatively consistently valued compared to other codes with similar time values and a global period of XXX. We proposed the RUC-recommended direct PE inputs without refinement.

We received public comments on the CT Head-Brain (CPT codes 70450, 70460, and 70470). The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to adopt the RUC-recommended work RVUs and PE inputs.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing as proposed work RVUs of 0.85, 1.13, and 1.27 for CPT codes 70450, 70460, and 70470 respectively.

(25) Screening CT of Thorax (CPT Codes 71250, 71260, 71270, and 71271)

In October 2018, AMA staff identified the CMS/Other Source codes with 2017 Medicare utilization over 30,000. HCPCS code G0297 (*Low dose ct scan (ldct) for lung cancer screening*) was identified. In January 2019, the RUC recommended to refer to CPT Editorial Panel to establish a permanent code for this procedure. In May 2019, the CPT Editorial Panel revised three codes and added one code to distinguish diagnostic computed tomography, thorax from computed tomography, thorax, low dose for lung cancer screening.

For CPT code 71250 (*Computed tomography, thorax; without contrast material*), we did not propose the RUC recommendation to maintain the current work RVU of 1.16 as we believe this does not accurately reflect the reduction in physician work time, and because an analysis of all XXX-global period codes with similar time values indicates that this service is overvalued. Instead, we recommended proposing a work RVU of 1.08 based on the ratio of current to RUC-recommended intraservice time. As support for this value, we note that it falls slightly below CPT code 76391 (*Magnetic resonance (e.g., vibration) elastography*), which has a work RVU of 1.10 and also has higher physician time values.

Similarly, for CPT code 71260 (*Computed tomography, thorax; with contrast material(s)*), we did not propose the RUC recommendation to maintain the current work RVU of 1.24 as we believe this does not accurately reflect the reduction in physician time, and proposed a work RVU of 1.16 based the ratio of current to RUC-recommended intraservice time. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference between CPT codes 71250 and 71260 is equivalent to the RUC-recommended interval of 0.08 RVUs. As stated previously, we noted

that we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We noted that the proposed work RVU of 1.16 maintains the RUC-recommended interval of 0.08 additional RVUs above our proposed work RVU of 1.08 for CPT code 71250.

For CPT code 71270 (*Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections*), we did not propose the RUC recommendation to maintain the current work RVU of 1.38 as we believed this does not accurately reflect the reduction in physician time, and instead, we proposed a work RVU of 1.25 with a crosswalk to CPT code 93284 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system*) and we supported this value by noting that it is slightly higher than values suggested by the ratio of current to RUC-recommended intraservice time For CPT code 71271 (*Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)*), we did not propose the RUC-recommended work RVU of 1.16, but proposed a work RVU of 1.08 so that the value of this code is consistent with that of CPT code 71250 as current code G0297 is valued based on the value of CPT code 71250, and to maintain the relative relationship among these codes. In the CY 2016 PFS final rule (80 FR 70974) we finalized that CPT code G0297 should be identically valued to CPT code 71250.

We proposed the RUC-recommended direct PE inputs without refinement for CPT codes 71250, 71260, and 71270. For the direct PE inputs for CPT code 71271, we proposed 2 minutes for the clinical labor activity CA011: ''Provide education/obtain consent'' rather than the RUC-recommended 3 minutes to be consistent with other non-contrast screening codes, and we proposed 4 minutes for the clinical labor activity CA038 ''Coordinate post-procedure services'' rather than the RUC-recommended 6 minutes to be consistent with other screening services, and because we did not see any compelling evidence that this service has changed significantly since G0297 was implemented for CY 2015 to warrant the recommended 2 additional minutes.

We received public comments on the codes in the Screening CT of Thorax family. The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with the use of intraservice time ratios to account for changes in time, arguing that it negates CMS' longstanding position that we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs.

A commenter attributed the decreases in intra-service times for CPT codes 71250 and 71270 to survey variation. The commenter stated that reductions in pre and post-service time values do not necessarily justify a reduction in physician work value as intraservice work has a higher intensity than pre-service and post-service work. Additionally, the commenter stated that at these lower ends of time in the RBRVS, it is unreliable to draw conclusions based on single minute increments, which may simply be a result of rounding to whole integers.

Response: While we agree that the surveyed intraservice times are not substantially lower than they are currently, we disagree that the differences in total time values are negligible or that they should not be accounted for in work RVU. In addition, we note that we considered the RUC-recommended values based on the relationship between work RVU and time as well as through comparisons to other CPT codes of similar time values. We continue to believe that in light of this analysis, the RUC-recommended values are overestimations.

Comment: For CPT code 71250, a commenter disagreed with the use of a comparison to a magnetic resonance (MR) code with higher physician times, CPT code 76391 (*Magnetic resonance (e.g., vibration) elastography*). The commenter stated that this is a suboptimal comparison as CPT code 76391 involves work predominantly focused on a single organ (the liver) with, in general, a single pathology (fibrosis). In contrast, the commenter stated that CPT code 71250 requires evaluation of numerous structures in the thorax including the heart, lungs, mediastinum, pleura and pleural space, bones, etc. which can be affected by a multitude of pathologies. For CPT code 71260, the RUC objected to the CMS statement that the proposed work RVUs maintain the RUC-recommended relative difference between CPT codes 71250 and 71260, stating that time survey data and comparison codes, not ratios and intervals, were used in arriving at the value of 1.24 for CPT code 71260.

Response: We reiterate that a comparison to all XXX-global period codes with similar time values indicated that the RUC-recommended work RVU was overestimated for CPT code 71250. While we recognize that the RUC did not base its recommended valuation for CPT code 71260 on an incremental relationship, we continue to believe the use of an incremental difference between codes is a valid methodology for considering appropriate values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity.

Comment: For CPT code 71270, a commenter disagreed with the use of a crosswalk to CPT code 93284 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system*) because these codes describe completely different clinical work.

Response: We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: For CPT code 71271, the RUC noted that HCPCS code G0297 is CMS/Other sourced. Therefore, how the times and values were established is unknown or flawed. The RUC also agreed that the physician work involved in the new code for low-dose screening exam is comparable to the diagnostic exam performed in CPT code 71250. While CMS finalized a policy that HCPCS code G0297 should be identically valued to CPT code 71250 in the CY 2016 PFS final rule (80 FR 70974–70975), the G-code is currently not valued the same. CPT code 71250 is currently valued higher than HCPCS code G0297 because CPT code 71250 was revalued in 2016; its work RVU increasing from 1.02 to 1.16, however HCPCS code G0297 was not revalued at that time and remains currently valued at 1.02. The RUC suggested CMS to accept a work RVU of 1.16 for CPT code 71271 and requests deletion of HCPCS code G0297. In the event this G-code is

not deleted, the RUC requests that HCPCS code G0297 be crosswalked to 71271 and the same value and inputs be assigned.

Response: Our proposed work RVU of 1.08 for HCPCS code 71271 is partly based on our assumption that this code has an identical work RVU to CPT code 71250. Our proposed values will restore parity between the two codes by increasing the work RVU for the former to match our proposed value for the latter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Screening CT of Thorax family as proposed.

(26) X-Ray Bile Ducts (CPT Codes 74300, 74328, 74329, and 74330)

CPT codes 74300 (*Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation*) and 74328 (*Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*) were identified through a screen of CMS/Other Source codes with 2017 Medicare utilization over 30,000. CPT codes 74329 (*Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*) and 74330 (*Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*) were included as part of the same code family and the family was surveyed. The codes describe x-rays of the liver, pancreas, and bile ducts. They are performed in facilities and have no direct PE inputs.

We disagreed with the RUC-recommended work RVU of 0.32 for CPT code 74300. We proposed a work RVU of 0.27 based on a crosswalk to CPT code 74021 (*Radiologic examination, abdomen; 3 or more views*), one of the reference services from the RUC survey and that has an intraservice time of 4 minutes, nearly identical to the RUC's recommendation of 5 minutes of intraservice time for CPT code 74300. The proposal was supported by CPT code 93922 (*Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries*) with a work RVU of 0.25 and an intraservice time of 5 minutes and a total time of 10 minutes. These times are nearly identical to the RUC's recommended intraservice of 5 minutes and total time of 10 minutes for CPT code 74300.

We proposed the RUC-recommended work RVU of 0.47 for CPT code 74328 (*Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*), with an intraservice time of 10 minutes and a total time of 20 minutes.

We disagreed with the RUC's recommended work RVU of 0.50 for CPT code 74329 (*Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*). We proposed a crosswalk to CPT code 74328 at a work RVU of 0.47 because the intraservice and total times for both codes are identical and we noted that we believe the work involved in the biliary ductal and pancreatic ductal systems is similar.

We disagreed with the RUC's recommended work RVU of 0.70 for CPT code 74330 (*Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*) and we proposed a work RVU of 0.56 based on the proposal of the RUC's recommendation for CPT code 74328 to create internal consistency within the code family, based on our time ratio methodology and further supported by a reference to CPT code 93228 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*) with nearly identical and total time values to CPT code 74330.

The RUC did not recommend and we did not propose any direct PE inputs for these codes.

We received public comments on the X-Ray Bile Ducts code family. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support the proposal of 0.27 work RVUs for CPT code 74300, stating that based on the RUC survey data, the overall intensity and complexity to perform CPT code 74300 is greater than that required to perform the key reference service of CPT code 74021. Commenters also stated that the crosswalk to CPT code 74021 was inappropriate due to the service time difference between the codes.

Response: Based on the survey results, we disagree that the overall intensity and complexity to perform CPT code 74300 is greater than that required to perform CPT code 74021. Based on the survey results, only the technical skill component of intensity suggested that CPT code 74300 may be more intense than CPT code 74021, with 67 percent of respondents stating that CPT code 74300 was more intense. Comparing CPT code 74300 to its key reference service CPT code 74321, 50 percent of survey respondents reported that CPT code 74300 had identical intensity, 50 percent of survey respondents reported physical effort as having identical or less intensity, and 67 percent of survey respondents reported psychological stress as having identical or less intensity. We also disagree that the crosswalk to CPT code 74021 was inappropriate because the RUC used CPT code 74021 as a key reference survey in its survey. Thus, we are finalizing 0.27 work RVUs for CPT code 73400 as proposed.

Comment: A few commenters supported the CMS proposal of 0.47 work RVUs for CPT code 74328.

Response: We appreciate commenters' support and are finalizing 0.47 work RVUs for CPT code 74328 as proposed.

Comment: A few commenters did not support the proposal of 0.47 work RVUs for CPT code 74329. These commenters asserted that the work associated with assessing the pancreatic ductal system in CPT code 74329 and is more intense and complex than CPT code 74328. They also stated that codes with identical times are not assigned the same RVU because both the AMA RUC and CMS recognize that procedures with equivalent times do not have equivalent intensities.

Response: While it may be true that codes that have identical times can have different intensities, because the survey did not use CPT code 74328 as a key reference service for the valuation of CPT code 74329, we do not believe the survey results provided sufficient evidence to support the assertion that CPT code 74329 is more intense. Thus, we are finalizing 0.47 work RVUs for CPT code 74329 as proposed.

Comment: A few commenters did not support the proposal of 0.56 work RVUs for CPT code 74330. These commenters were concerned that we did not apply our time ratio methodology correctly. The commenters also disagreed with the use of time ratio methodologies for work valuation for these services. Commenters stated that this use of time ratios is not a valid methodology for the valuation of physician services.

Response: To clarify, we used an intraservice time ratio and not a total time ratio. We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for PFS services.

We have responded to concerns about our methodology earlier in this section

of this final rule. For additional information regarding the use of use of time ratios in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Thus, we are finalizing 0.56 work RVUs for CPT code 74330 as proposed.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the X-Ray Bile Ducts family as proposed. We did not propose and we are not finalizing any direct PE inputs for these codes.

(27) Venography (CPT Codes 75820 and 75822)

The review of CPT code 75820 (*Venography, extremity, unilateral, radiological supervision and interpretation*) was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 20,000 claims in a year. CPT code 75820 currently has a work RVU of 0.70 with 14 minutes of total time. This service involves the supervision and interpretation of a contrast injection and imaging of either the upper or lower extremity. For CPT code 75820, the RUC recommended 12 minutes preservice time, 20 minutes intraservice time, 10 minutes postservice time and 42 minutes of total time. The specialty societies' survey at the 25th percentile yielded a 1.05 work RVU, and it is the RUC's recommended work value. We proposed the RUC-recommended value for CPT code 75820.

CPT code 75822 (*Venography, extremity, bilateral, radiological supervision and interpretation*) is reviewed as part of the family of codes included with CPT code 75820. CPT code 75822 has a current 1.06 work RVU and 21 minutes of total time. The RUC recommended 15 minutes preservice time, 30 minutes intraservice time, 12 minutes postservice time and 57 minutes of total time, and the survey's 25th percentile work RVU of 1.48. The service is similar to CPT code 75820, except that this CPT code is bilateral, involving the supervision and interpretation of a contrast injection and imaging of both of either the upper or lower extremities. The RUC recommended 1.48 work RVU and 57 minutes of total time for CPT code 75822. We proposed these RUC-recommended values for CPT code 75822.

We received public comments on the Venography services CPT codes 75820 and 75822. The following is a summary of the comments we received and our responses.

Comment: The commenters appreciated CMS' proposal of the AMA RUC recommended RVU values.

Response: We appreciate the commenters' support for our proposal to adopt the RUC recommendations for CPT codes 75820 and 75822.

After consideration of the public comments, we are finalizing the RUC recommendations for CPT codes 75820 and 75822, as proposed.

(28) Introduction of Catheter or Stent (CPT Code 75984)

The RUC recommended reviewing CPT code 75984 (*Change of percutaneous tube or drainage catheter with contrast monitoring (e.g., genitourinary system, abscess) radiological supervision and interpretation*) after more utilization data was available, which resulted in this service being surveyed and reviewed for the April 2019 RUC meeting. We proposed the work RVU of 0.83 as recommended by the RUC. We proposed the RUC-recommended direct PE inputs for CPT code 75984 without refinement.

We received public comments on the Introduction of Catheter or Stent family (CPT code 75984). The following is a summary of the comments we received and our responses.

Comment: Commenters supported the CMS proposal of 0.83 for the work RVU as recommended by the RUC, as well as the proposal of the direct PE inputs without refinements.

Response: We appreciate the commenters' support for our proposal to adopt the RUC recommendations for CPT code 75984.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 0.83 for CPT code 75984. We are also finalizing the RUC-recommended direct PE inputs for CPT code 75984 without refinement.

(29) Medical Physics Dose Evaluation (CPT Code 76145)

The CPT Editorial Panel created CPT code 76145 (*Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report*), which is a new PE-only code. Because of the high amount of clinical staff time and the fact that there are not analogous services, the PE Subcommittee requested that the specialty societies conduct a PE survey. In addition, they stated that the service is stand-alone, meaning that the medical physicist works independently from a physician and there are no elements of the PE that are informed by time from a physician work survey. Following the meeting, the specialty societies developed a PE survey which was reviewed and approved by the Research Subcommittee. We proposed the RUC-recommended direct PE inputs for CPT code 76145 without refinement.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal to implement the RUC-recommended direct PE inputs for CPT code 76145 without refinement.

Response: We appreciate the support for our proposals from the commenters.

Comment: Commenters recommended that CMS remove the Deficit Reduction Act (DRA) cap designation for CPT code 76145, stating that this is not an imaging service but a patient-specific organ dose assessment and evaluation performed by a medical physicist that can be utilized across a broad spectrum of cardiology and interventional radiology services. These dose calculations are commonly associated with interventional procedures and not diagnostic imaging studies.

Response: We are persuaded by the commenters that this service does not describe an imaging service as defined for purposes of the ''DRA cap,'' also known as the ''OPPS cap,'' under section 1848(b)(4)(B) of the Act. We note it is more akin to physics consultation services similar to those described by CPT codes 77331 (*Special dosimetry (e.g., TLD, microdosimetry) (specify), only when prescribed by the treating physician*), 77336 (*Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy*), and 77370 (*Special medical radiation physics consultation*). Therefore, we are not including CPT code 76145 within the codes that are subject to the adjustment under section 1848(b)(4) will not be subject to the OPPS cap.

After consideration of the public comments, we are finalizing the direct PE inputs for CPT code 76145 as proposed and removing this code from the OPPS Cap List.

(30) Ophthalmic Ultrasound Anterior Segment (CPT Code 76513)

CPT code 76513 (*Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy*) was identified by the RUC due to volume growth, attributed to improved equipment. The CPT Editorial Panel has

since revised this code to clarify that it is either unilateral or bilateral (it was previously unilateral). It was then surveyed. The code describes a test for glaucoma and is performed on the same day as an office/outpatient evaluation and management (O/O E/M) visit. The CPT and RUC removed CPT code 76513 from its former code family, creating a family of 1 service.

In reviewing this code, we noted that the recommended total time is decreasing from 19 minutes to 15 minutes (21 percent) while the RUC-recommended work RVU is decreasing from 0.66 to 0.60 (9 percent). We did not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we noted we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 76513, we noted that we believe that it would be more accurate to propose a work RVU of 0.53 based on a crosswalk to CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*) with identical intraservice and total times.

For the direct PE inputs, we proposed to make two refinements to the clinical labor times of CPT code 76513. We proposed a reduction of 1 minute for the clinical labor task CA009: ''Greet patient, provide gowning, ensure appropriate medical records are available'' because the EHR information should already be linked from the preceding O/O E/M visit and the entry of information would be redundant and paid under indirect PE. We also proposed a reduction of 1 minute for the clinical labor task CA011: ''Provide education/obtain consent'' to be consistent with the time for this clinical labor task for the services in CPT code 76513's former code family.

We received public comments on CPT code 76513. The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with the CMS proposed work RVU of 0.53 and stated that CMS should finalize the RUC-recommended work RVU value of 0.60. Commenters stated that CPT code 76513 is more complex and intense than the proposed crosswalk of CPT code 74320 due to a wider number of potential diagnoses, and requires placing a probe with water bath on the patient's cornea, which is more uncomfortable than swallowing contrast, requiring extra skill and effort to obtain appropriate images.

Response: We appreciate the additional information from the commenters regarding the intensity of CPT codes 76513 and 74320. In light of this additional information, we agree with the commenters that the diagnostic ophthalmic ultrasound service described by 76513 may have a higher intensity than the radiologic examination service described by CPT code 74320. Therefore, we are finalizing the RUC-recommended work RVU of 0.60 for CPT code 76513.

Comment: A few commenters stated that the crosswalk or methodology used in the original valuation of CPT code 76513 is unknown and not resource-based, and therefore, it was invalid for CMS to compare the current time and work to the surveyed time and work.

Response: We appreciate the commenters' concerns regarding our interpretation of older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the most recent data available regarding work times, and we acknowledge that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed; we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: A few commenters disagreed with our reduction of 1 minute of clinical labor task CA009: ''Greet patient, provide gowning, ensure appropriate medical records are available'' and stated that our assumption that the EHR information should already be linked from the preceding O/O E/M visit was incorrect. Commenters stated that it is not typical for the EHR and the ultrasound equipment to be linked and that staff time is required to enter the data into the ultrasound equipment software and ensure that it matches the information in the main EHR and therefore it would be inappropriate to reduce the RUC-recommended staff time.

Response: While we appreciate the additional information that the EHR and the ultrasound equipment are not linked, we believe that the staff time required to enter the data into the equipment constitutes a data entry task and paid under indirect PE. Therefore, we are finalizing our proposed reduction of 1 minute of clinical staff time for CPT code 76513.

Comment: A few commenters also disagreed with our proposed reduction of 1 minute for the clinical labor task CA011: ''Provide education/obtain consent.'' Commenters stated that this test involves placement of a device directly onto the ocular surface, with a risk of corneal abrasion and associated loss of vision. Thus, a clear and detailed explanation of what to expect was necessary to reduce patient anxiety and increase the patient's ability to cooperate with the exam. Thus, patient consent would require the RUC-recommended 3 minutes.

Response: We appreciate the additional information from the commenters regarding the steps that are involved in providing education and obtaining consent and we agree with the commenters that the additional minute of time would be required. Thus, we are finalizing the RUC-recommended 3 minutes of clinical staff time.

After consideration of the public comments, we are not finalizing our proposed work RVU of 0.53 for CPT code 76513 and are instead finalizing the RUC-recommended work RVU of 0.60. We are finalizing the direct PE inputs as proposed, with the exception of the proposed reduction of 1 minute for the clinical labor task CA011 as detailed above.

(31) Dual-Energy X-Ray Absorptiometry (CPT Code 77080)

We did not make any proposals regarding CPT code 77080 (*Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)*) in the proposed rule. Following the publication of the CY 2021 PFS proposed rule, a stakeholder contacted CMS and stated that Medicare payment for the CPT code 77080 has declined in the nonfacility setting from $140 in 2006 to approximately $40 in 2020. The stakeholder stated that due to policies proposed in the CY 2021 PFS proposed rule, payment for DXA would be subject to an eight percent decrease bringing the payment rate to $36.78. The stakeholder

suggested CMS to address DXA payment in the CY 2021 PFS final rule.

In response to the stakeholder, we note that the payment decreases for CPT code 77080 were produced by two factors: The adoption of the current PE methodology during CY 2007–2010 and the code's last RUC review in CY 2014. Payment for CPT code 77080 has been stable at approximately $40 for the last 6 years. We also note that our ratesetting methodology proposed a modest increase in total RVUs for CY 2021 for CPT code 77080. However, the proposed decrease of 10.6 percent to the CF resulted in the proposed payment for CPT code 77080 decreasing by approximately eight percent. This decrease would result from implementation of budget neutrality adjustment to the PFS conversion factor, and would not be caused by any policy changes associated with CPT code 77080. We remind stakeholders that, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs under the PFS cause expenditures for the year to change by more than $20 million, we are statutorily obligated to make budget neutrality adjustments to ensure that expenditures do not increase or decrease by more than $20 million. For additional information, we direct readers to the Regulatory Impact Analysis (section VIII.) of this rule. We may consider future rulemaking regarding CPT code 77080 under the misvalued code initiative if there is continued stakeholder concern regarding the valuation of this service.

(32) Radiation Treatment Delivery (CPT Code 77401)

CPT code 77401 (*Radiation treatment delivery, superficial and/or ortho voltage, per day*) was identified by the RUC Relativity Assessment Workgroup through a screen of high-volume growth, for services with 2017 Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2012 through 2017. In January 2019, the RUC recommended to refer to this service to the CPT Editorial Panel to better define the set of services associated with delivery of superficial radiation therapy (SRT).

We proposed the following direct PE refinements: A reduction of 2 minutes for the clinical labor task CA024: ''Clean room/equipment by clinical staff,'' to the standard 3 minutes, and we did not propose to include the new equipment item ER119 ''Lead Room,'' as we noted that we did not have enough information on what this equipment item contains, and we are requesting more information to allow us to determine if it is more accurately priced as direct or indirect PE. CPT code 77401 is a PE only code and we proposed to maintain the current work RVU of 0.00.

We received public comments on the Radiation Treatment Delivery (CPT code 77401). The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that while they still believe more should be done with regard to the work RVUs for 77401 in order to make this treatment option more fair and equitable, the commenters greatly appreciate CMS' willingness to increase the PE RVUs for SRT. The commenters stated that this is a much needed increase for the modality as a whole and should result in an increase in availability for patients that truly need access to this technology for non-melanoma skin cancer and keloids.

Response: We appreciate the support for our proposals from the commenters.

Comment: Commenters provided information on the recommended new equipment item ER 119 (''Lead Room''), noting that all states require a lead shielded room for radiation therapy. Some commenters said that physicians can also utilize this room for other services when not using the SRT. Some commenters stressed that although the lead lined room may be used for other services when there is no patient receiving superficial radiation therapy (SRT), there should not be payment for the lead room when SRT is not being performed.

Response: We continue to believe that, given the fact that the lead-shielded room may be used for other types of services as indicated by commenters, this item is not allocable specifically to CPT code 77401, but is rather a general practice cost akin to office rent expenses. Therefore, we consider the lead-shielded room to be indirect PE, and we are finalizing the direct PE inputs as proposed, without including the lead lined room.

Comment: Commenters disagreed with the proposed reduction of 2 minutes for the clinical labor task CA024: ''Clean room/equipment by clinical staff'', to the standard 3 minutes. Commenters stated that the 2 minutes were added by the RUC because the room and the equipment must be cleaned after each use and this has increased at least 5 fold under COVID. Commenters stated that the standard 3 minutes is for the room only and is insufficient to do both and that CMS should restore the 2 minutes that were removed.

Response: The commenters stated that 5 minutes are necessary to clean both the room and the equipment; however, the standard time of 3 minutes already assumes that both the room and equipment will be cleaned. Therefore, we are finalizing this PE refinement as proposed.

After consideration of the public comments, we are finalizing the direct PE inputs for this service as proposed.

(33) Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

In April 2018, the RUC's Relativity Assessment Workgroup (RAW) identified CPT code 77522 (*Proton treatment delivery; simple, with compensation*) and CPT code 77523 (*Proton treatment delivery; intermediate*) as contractor-priced Category I CPT codes with 2017 estimated Medicare utilization over 10,000 services. Although the RAW agreed with the specialty society that this family of codes should remain contractor priced, the RUC determined that these services should be surveyed for PE. CPT codes 77520 (*Proton treatment delivery; simple, without compensation*) and 77525 (*Proton treatment delivery; complex*) were added to the family and the group was surveyed for PE for the April 2019 RUC meeting.

We noted in the proposed rule that we encountered significant difficulties in reviewing the recommended direct PE inputs for the codes in the Proton Beam Treatment Delivery family. These difficulties were largely associated with determining a price for the two new equipment items in the code family, the Proton Treatment Vault (ER115) and the Proton Treatment Delivery System (ER116). These equipment items had extraordinarily high prices of $19,001,914 and $30,400,000 respectively on the invoices submitted with the code family. By way of comparison, the highest equipment price currently existing in our database for CY 2021 is the ''SRS system, Linac'' (ER082) equipment item at $4,233,825. We noted concerns that establishing equipment pricing for the proton treatment vault and delivery system at a rate that is so much higher than anything else in our equipment database could distort relativity.

We also noted concerns about the information provided on the submitted invoices used for the pricing of these two new equipment items. The invoices for both the Proton Treatment Vault and the Proton Treatment Delivery System contained building construction costs such as asphalt paving, masonry and carpentry expenses, drywall packaging, and the installation of electrical

systems. We noted that we understood that these proton treatment equipment items are extremely capital-intensive and require the construction of custom-built offices to house the equipment. However, the expenses associated with constructing new office facilities fall outside of our direct PE methodology, and would be more accurately classified as a form of building maintenance or office rent under indirect PE. We did not agree that construction costs should be included as a form of direct PE because they are not individually allocable to a particular patient for a particular service. Although we agreed that the proton beam treatment practitioners do need to bear the costs associated with the storage of this equipment, we noted that this is a form of indirect PE under our methodology. Therefore, we noted that we did not believe that it would serve the interests of relativity to include these building construction costs for the proton treatment equipment as a type of direct PE expense.

As a result, we proposed to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525 instead of proposing active pricing for these services. We noted that we believe that maintaining contractor pricing will allow the limited providers of these very expensive services to adapt more quickly to shifts in the market-based costs associated with the proton treatment equipment. The RUC similarly expressed concern in its recommendations about the extremely high cost of this equipment, agreed that these services were extremely hard to value, and noted the difficulties that had taken place in surveying the family of codes. The recommendations from the RUC also noted that proton treatment is a rapidly changing technology and the change in the treatment equipment often requires extensive modification to the vault. We also noted that we believe that these frequent changes can be more accurately captured through contractor pricing as opposed to the need to update the pricing of the proton treatment equipment on an annual basis.

As discussed in the proposed rule, if we were to propose active pricing for the codes in this family, we believe that we would need to remove the building construction costs from the Proton Treatment Vault and the Proton Treatment Delivery System as forms of indirect PE, which would substantially lower their overall equipment prices. We would also refine the equipment times to the standard formula for highly technical equipment, which would result in 3 minutes less time for each equipment item (such as 14 minutes for all three equipment items in CPT code 77522).

We received public comments on the codes in the Proton Beam Treatment Delivery family. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525 instead of proposing active pricing for these services. Commenters stated that they applauded CMS for carefully considering the unintended consequences of pricing high equipment cost items using the current CMS methodology and agreed that contractor pricing will allow proton therapy practitioners to adapt quickly to shifts in the market-based costs associated with the proton treatment equipment. Commenters stated that until there is a way to accurately reflect the price of this advanced technology, they agreed with the proposal and requested that CMS maintain contractor pricing for the proton treatment delivery codes.

Response: We appreciate the support for our proposals from the commenters.

Comment: One commenter stated that although they currently supported the continuation of contractor pricing, the commenter also could envision proton beam treatment pricing at some percentage of OPPS rates (*e.g.,* 95 percent of OPPS payment amount) as CMS looks to potentially value PE RVUs using OPPS rates. The commenter stated that while this rate might not adequately cover the PE component in some larger facilities, it would allow continued support for other facilities showing significant positive patient outcomes.

Response: We appreciate the feedback from the commenter regarding the potential use of OPPS payment rates for PFS pricing.

Comment: One commenter disagreed with the CMS proposal to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525 and recommended that CMS finalize the RUC recommendations. The commenter stated that although it is not the purview of the RUC to make recommendations about pricing and useful life of equipment, CMS should accept the direct PE inputs for CPT codes 77520, 77522, 77523, and 77525 as submitted by the RUC.

Response: We disagree with the commenter and continue to believe that the unique nature of the equipment costs associated with these services poses problems for our PE methodology. We believe that maintaining contractor pricing will incorporate these costs into the payment rate while also allowing the limited practitioners of these very expensive services to adapt more quickly to shifts in the market-based costs associated with the proton treatment equipment.

After consideration of the comments, we are finalizing our proposal to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525.

(34) Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS Codes G0008, G0009, and G0010)

Especially in the context of the current PHE for COVID–19, it is evident that consistent beneficiary access to vaccinations is vital to public health. Many stakeholders have raised concerns regarding the reductions in payment rates for vaccine administration services over the past several years. The codes that describe these services have generally been valued based on a direct crosswalk to CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Because we proposed and finalized reductions in valuation for that code for CY 2018 and because the reductions in overall valuation have been subject to the multi-year phase-in of significant reductions in RVUs, the payment rate for the vaccine administration codes has been concurrently reduced.

In the CY 2020 PFS final rule, we acknowledged that it is in the public interest to ensure appropriate resource costs are reflected in the valuation of the immunization administration services that are used to deliver vaccines, and noted that we planned to review the valuations for these services in future rulemaking. For CY 2020, we maintained the CY 2019 national payment amount for immunization administration services described by HCPCS codes G0008 (*Administration of influenza virus vaccine*), G0009 (*Administration of pneumococcal vaccine*), and G0010 (*Administration of hepatitis b vaccine*) in the interim.

The RUC has recently resubmitted recommendations from 2009 regarding the appropriate valuation for the broader range of vaccine administration services, including CPT codes 90460 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered),* 90471 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular*

injections); 1 vaccine (single or combination vaccine/toxoid)), and 90473 (*Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)*). In its recommendation, the RUC noted that the current RVUs assigned are directly crosswalked from CPT code 96372 (like the vaccine administration G-codes had been) and the resulting payment rates are substantially lower than current Centers for Disease Control and Prevention (CDC) regional maximum charges. The RUC also pointed out that appropriate payment for immunization administration that reflects resource cost is critical in maintaining high immunization rates in the United States, as well as having the capacity to respond quickly to vaccinate against preventable disease outbreaks.

We agreed with the RUC's assertions regarding the importance of appropriate resource-based valuations for vaccine administration services. We also recognized that the importance of these services is increased in the context of the current PHE for COVID–19, especially should there be a vaccine for this particular disease.

We reviewed and considered the 2009 RUC-recommended direct PE inputs for CPT codes 90460–90474 (as well as the related G-codes) in place of the existing policy, based on a crosswalk to CPT code 96372. However, the RUC-recommended direct PE inputs from 2009 would result in significant decreases in valuation for these 6 CPT codes, even compared to the current crosswalk. At the time of the proposed rule, we did not believe that either the existing crosswalk or the RUC recommendations from over a decade ago reflect the relative resource costs associated with these services. Without updated information to use in developing rates specific to these codes based on direct PE inputs, and in consideration of the importance of these services for Medicare beneficiaries, as well as the public health concerns raised by commenters, we believed that it would be most appropriate to value these services using a crosswalk methodology that better reflects the relative resources involved in furnishing all of these services.

Therefore, we proposed to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000 (*Introduction of needle or intracatheter, vein*). CPT code 36000 is a service with a nearly identical work RVU (0.18 as compared to 0.17 for CPT codes 90460, 90471, and 90473) and a similar clinical vignette. We noted that we believe that the additional clinical labor, supply, and equipment resources associated with the furnishing of CPT code 36000 more accurately capture the costs associated with these immunization codes. We also noted that this crosswalk would result in payment rates for vaccine administration services at approximately the same CY 2017 rates that were paid prior to the revaluation of CPT code 96372, which had previously served as the basis of the crosswalk. We noted that we believe that the proposed crosswalk is the most accurate valuation of these services and would also serve to ensure the appropriate relative resources involved in furnishing all of these services is reflected in the payment for these critical immunization and vaccination services in the context of the health needs of Medicare beneficiaries.

Regarding the add-on codes associated with these services, CPT codes 90461 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered*), 90472 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)*), and 90474 (*Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)*), we noted that the previous valuation methodology set their RVUs at approximately half of the valuation for the associated base codes, described above. Absent additional information, we proposed to maintain that approach by valuing the three add-on codes at half of the RVUs of the aforementioned crosswalk to CPT code 36000.

Finally, we proposed this valuation to apply to all of these existing vaccine administration codes, using the valuation of CPT code 90471 for base codes and CPT code 90472 for add-on codes. We also noted that should a vaccine for COVID–19 or other infectious disease become available during CY 2021, we would anticipate applying the same approach to valuing the administration of such vaccines, regardless of whether separate coding for such services would need to be introduced.

We received public comments on the codes in the Immunization Administration family. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000. Commenters stated that the current vaccine administration rates do not adequately cover the costs of purchasing, storing, monitoring, and administering vaccines and that appropriate valuation and reimbursement for these services is critical to ensuring widespread access to vaccines. Commenters agreed that the current crosswalk does not recognize the resources needed to provide the immunization procedure and that the proposed crosswalk to CPT code 36000 more accurately captures the direct clinical labor and resources needed to perform immunizations.

Response: We appreciate the support for our proposals from the commenters.

Comment: Many commenters supported the proposal to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000 while also disagreeing with the proposal to value the three add-on codes (CPT codes 90461, 90472, and 90474) at half of the RVUs of the aforementioned crosswalk to CPT code 36000. Commenters stated that the value of the work RVU for the add-on Immunization Administration codes is not half of the base codes but rather 88 percent of the value of the base codes. Commenters requested that CMS apply the same magnitude relationship between the base and add-on codes as in the previous valuation.

Response: We appreciate the feedback from the commenters regarding the relationship between the base codes and add-on codes in this family. After reviewing the issue and looking at the historic relationship in payment rates for the base codes and add-on codes, we agree with the commenters that the add-on codes have typically been valued at 88 percent of the RVU of the base codes, not half of the value. Therefore, we are finalizing the value of the three add-on codes at 88 percent of the RVUs assigned to the immunization administration codes.

Comment: Several commenters stated that they supported the proposals for this code family; however, they noted that there has been some confusion about the actual payment amount because RVUs for the CMS-issued immunization administration HCPCS ''G'' codes are not listed in the files sent to the contractors nor made available to the public. The commenters suggested CMS to include the crosswalked values for the immunization codes in the RVU files to ensure that the crosswalk is accurately implemented, and that stakeholders can identify the rate

Medicare will pay for vaccine administration.

Response: HCPCS codes G0008, G0009, and G0010 are used to bill Medicare for administration of the preventive vaccines described under section 1861(s)(10) of the Act. They are not technically valued under the PFS, as they do not fit within the statutory definition of physicians' services in section 1848(j)(3) of the Act. CMS established HCPCS codes G0008, G0009, and G0010 to describe the administration of these preventive vaccines. As a result, no RVUs or payment amounts are shown for these codes in the PFS tables, and payment for them is not made under the PFS. While it is true that we have established payment rates for these codes using a crosswalk to the values of codes listed on the PFS, these three HCPCS codes do not have PFS rates themselves.

Comment: Several commenters requested that in the future CMS should ensure a long-term sustainable valuation for vaccine administration by severing any linkage to other non-related CPT codes. The commenters recommend CMS consider determining the value of vaccine administration codes based on actual, updated physician time and PE inputs for vaccine administration.

Response: We agree with the commenters that it would be helpful to be able to value the vaccine administration codes using direct PE inputs instead of relying on crosswalks to other services; however, as we mentioned in the proposed rule, we reviewed and considered the 2009 RUC-recommended direct PE inputs and found that they would result in significant decreases in valuation for the six vaccine administration CPT codes, even compared to the current crosswalk. We would welcome the results of an updated formal review of these services as well as any additional information that may be helpful for improved valuation.

Comment: Several commenters supported the proposal and further suggested CMS to use its available authority to make this proposed change in vaccine administration valuation effective prior to January 1, 2021. Commenters stated that timely and appropriate payment for immunization administration that reflects resource cost is critical in maintaining high immunization rates in the United States as well as having the capacity to respond quickly to vaccinate against preventable disease outbreaks.

Response: While we share the concerns of the commenters regarding the importance of appropriate payment for vaccine administration, this final rule takes effect beginning for CY 2021. We did not propose to modify payment policies for these services for any earlier timeframe and we continue to believe that the payment policies that we finalized last year were appropriate for these services.

Comment: One commenter stated that Medicare pays a travel allowance to cover the transportation and personnel expenses for specimen collection from an individual or a patient in an inpatient facility other than a hospital. The commenter recommended that CMS establish a travel fee for providers/practitioners of current adult vaccines and for COVID–19 vaccinations to support access to immunizations, following the same approach and with the same value as established for specimen collection.

Response: Travel and transportation fees are considered to be a form of indirect PE under our methodology and would not be included as a direct cost. Therefore, we do not believe it would be appropriate to establish a separate payment for these costs under the PFS or otherwise.

Comment: One commenter disagreed with the rationale that CMS provided to crosswalk the PE RVUs for this set of codes to equal those for CPT code 36000. The commenter stated that CPT code 36000 is a bundled service that is not recognized for payment by CMS, nor has it ever been reviewed by the RUC; and this code includes a multispecialty visit pack that would be a duplication of resources for the vaccination codes, and that also includes an angiocatheter, which would never be used for vaccine administration. The commenter stated that arbitrarily assigning a specific PE RVU to this set of vaccination codes was another example of CMS's failure to consistently apply the same standards to all codes in the PFS, and as such, takes payment for resources away from one group of health care providers and assigns it to another group of health care providers.

Response: We note that our proposal to crosswalk valuation for the vaccine administration services was based on methodological approaches that have long been used for valuation under the PFS and reflect our best estimate of resource cost for these services at the time of the proposal. As we mentioned in the proposed rule, we reviewed and considered the 2009 RUC-recommended direct PE inputs and found that they would result in significant decreases in valuation for the six vaccine administration CPT codes, even compared to the current crosswalk. We would welcome the results of an updated formal review of these services as well as any additional information that may be helpful for improved valuation.

After considering the comments, we are not finalizing our proposal to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000. We are instead finalizing a policy to maintain the CY 2019 payment for all nine of the services in this family, including the add-on codes. We note that maintaining the CY 2019 rates for these services will also maintain the historical relationship between the base administration codes and the add-on CPT codes 90461, 90472, and 90474, instead of our proposal to value the add-on codes at 50 percent of the base codes. As previously discussed, in our proposal, we approximated a cost for these services, but acknowledge the concerns that were raised in the comments we received and will continue to seek additional information that specifically reflects the resource costs and inputs that should be considered to establish payment for these services on a long-term basis. Again, we would welcome the results of an updated formal review of these services as well as any additional information that may be helpful for valuation in the immediate future.

(35) Liver Elastography (CPT Code 91200)

CPT code 91200 (*Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report*) was targeted for review through the RUC's new technology/new services screen. The RUC reviewed 3 years of available Medicare claims data (2016, 2017 and 2018) and surveyed the code for the January 2020 meeting.

We proposed the RUC-recommended work RVU of 0.21. We also proposed the RUC-recommended direct PE inputs for CPT code 91200 without refinement.

We received public comments on CPT code 91200. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal of the RUC-recommended work RVU and direct PE inputs for CPT code 91200.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters discussed the clinical benefits of liver elastography treatments using Fibroscan equipment. Commenters stated that this service expedites patient diagnosis and keeps care centered in the office while allowing for non-invasive screenings of this population to identify those

patients with advanced fibrosis and cirrhosis who are at high risk for complications and costly care, allowing for earlier successful outpatient intervention. Commenters recommended that Fibroscan reimbursement should be increased, not decreased, which will allow expanded utilization and access for more GI physicians providing more widespread use of this effective and non-invasive practice based technology.

Response: We appreciate the additional information provided by commenters regarding the clinical benefits of the technology. However, the PFS is a resource-based payment system and we agree with the RUC that the resources associated with furnishing this service have decreased over time as the technology has become more widespread.

Comment: Several commenters disagreed with the proposed price for the Fibroscan with printer (ER101) equipment. Commenters stated that the proposed price of $102,495 is not supported by customer invoices or StrategyGen's market research and that there is no available data that supports a 31 percent reduction in equipment pricing. The commenters recommended pricing the ER101 equipment at $136,449 based on the submission of seven new invoices. The commenters stated that the average cost on the invoices was $180,000, which included hardware costs and service contracts, and their recommended pricing of $136,449 included the cost for CAP, which is an integral FibroScan component and not an optional addition. This price also included training and an S+ probe.

Response: We appreciate the additional information provided by the commenters, especially the submission of invoices for use in pricing the Fibroscan equipment. Based on this additional information, we agree with the commenters that the CAP is an integral part of the Fibroscan equipment and should be included in the price of the equipment. However, training expenses are an indirect cost under our PE methodology and therefore are not included in the price of the equipment. We also noted that the S+ probe was only included on 2 of the 7 submitted invoices and as a result we do not believe that this is typically part of the cost of the Fibroscan equipment. (By contrast, the CAP option was present in all cases.) Therefore, we are finalizing an update in the price of the Fibroscan (ER101) to $125,096.21 based on an average of six invoices, as we were unable to use one invoice since it did not have individually itemized costs.

Comment: Several commenters stated that Medicare and commercial payor utilization data for CPT code 91200 demonstrate that the usage of FibroScan in the physician office setting is well below 50 percent. Commenters stated that at a 50 percent usage rate, each FibroScan would generate 6,250 exams per year, or 24 per day, resulting in 3,656,250 total national exams per year but the Medicare database identifies 39,556 actual in-office claims in 2018 and 51,000 in 2019, resulting in less than 1 scan per day. Commenters stated that CMS can assign an equipment utilization rate of lower than 50 percent and the change is warranted by actual claims data. Commenters requested that CMS establish an equipment utilization rate of 10 percent for CPT code 91200.

Response: We disagree with the commenters that an equipment utilization rate of 10 percent would be typical for the Fibroscan. We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act. It would distort relativity to assign a utilization rate of 10 percent for the Fibroscan equipment which would have the same effect as a fivefold increase in the price of the equipment. We continue to agree with the RUC's recommended direct PE inputs for CPT code 91200.

After considering the comments, we are finalizing the RUC-recommended work RVU of 0.21 and the RUC-recommended direct PE inputs for CPT code 91200. We are also finalizing an update in the price of the Fibroscan (ER101) equipment to $125,096.21.

(36) Remote Retinal Imaging (CPT Codes 92227, 92228, and 92229)

The AMA CPT Editorial Panel revised CPT code 92227 (*Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral*) and CPT code 92228 (*Imaging of retina for detection or monitoring of disease; with remote physician or qualified health professional review and report, unilateral or bilateral*) that are reported for the treatment of diabetic retinopathy. Two practice sites are involved in these services: The acquiring site (for example, a primary care practice) and the reading site (for example, the ophthalmology practice). Both codes can be used to report diagnostic and monitoring services and the distinction is in whom provides the service: Physician (CPT code 92228) or clinical staff only (CPT code 92227). Thus, only CPT code 92228 includes work, accounting for the physician at the reading site. For both CPT codes 92227 and 92228, direct PE pays for the clinical staff at both sites.

The AMA CPT Editorial Panel also created CPT code 92229 (*Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral*) for point-of-care automated analysis that uses innovative artificial intelligence technology to perform the interpretation of the eye exam, without requiring that an ophthalmologist interpret the results. CPT code 92229 can be used at a primary care practice site and the artificial intelligence technology interprets the test instead of a remotely located ophthalmologist. Because no physician is involved, this service is PE only. We considered CPT code 92229 to be a diagnostic service under the PFS and are created separate payment for it.

For CPT code 92228, we proposed the RUC's recommended work RVU of 0.32. CPT codes 92227 and 92229 are PE only codes, and proposed a work RVU of 0.00 for both codes.

For both CPT codes 92227 and 92228, we proposed the AMA RUC's recommended direct PE inputs. We proposed two refinements to the direct PE inputs for CPT code 92229. We proposed a reduction of 1 minute for the clinical labor task CA009, ''Greet patient, provide gowning, ensure appropriate medical records are available,'' to be consistent with the amount of clinical labor for this task in CPT codes 92228 and 92227. We did not propose the RUC's recommendation of a $25 ''per click'' analysis fee for remote imaging because we considered this a service fee that constitutes a form of indirect PE and that this cost is appropriately captured via the indirect PE methodology as opposed to being included as a separate direct PE input. We did not believe that the analysis fee would be allocated to the use of an individual patient for an individual service, and can be better understood as an indirect cost similar to other administrative expenses.

We received public comments on the Remote Retinal Imaging family. The following is a summary of the comments we received and our responses.

Comment: For CPT code 92228, a few commenters supported our proposals for 0.32 work RVUs with no refinements to the direct PE inputs.

Response: We appreciate the commenters' support and are finalizing 0.32 work RVUs and no refinements to the direct PE inputs as proposed.

Comment: For CPT code 92227, a few commenters supported our proposals for 0.00 work RVUs with no refinements to the direct PE inputs.

Response: We appreciate the commenters' support and are finalizing 0.00 work RVUs with no refinements to the direct PE inputs as proposed.

Comment: We received no comments on our proposal for 0.00 work RVU for CPT code 92229.

Response: We are finalizing 0.00 work RVUs for CPT code 92229 as proposed.

Comment: Several commenters disagreed with our proposals for the direct PE inputs for CPT code 92229. A few commenters disagreed with our reduction of 1 minute of clinical labor task CA009: ''Greet patient, provide gowning, ensure appropriate medical records are available.'' Commenters stated that it is not typical for the EHR and the imaging and analyzing software to be linked and that staff time is required to enter the data into the imaging and analyzing software and ensure that it matches the information in the main EHR and therefore it would be inappropriate to reduce the RUC-recommended staff time.

Response: While we appreciate the additional information that the EHR and the imaging and analyzing software are not linked, we believe that the staff time required to enter the data into the imaging and analyzing constitutes a data entry task and is paid under indirect PE. Therefore, we are finalizing our proposed reduction of 1 minute of clinical staff time for CPT code 92229.

Comment: Several commenters also disagreed with the elimination of the analysis fee for remote imaging. They asserted that the analysis fee is a direct cost because it is directly attributable to a specific patient and incurred for each patient. The commenters also stated that because the analysis is conducted by artificial intelligence (AI) software, there would be no service if the software was not used on a per patient basis.

Response: As the PE data have aged and AI applications are emerging, we recognize that issues involving the use of AI are complex. While we agree that the costs for AI applications should be accounted for in payment, AI applications are not well accounted for in our PE methodology. In recent years, we have considered other services that use algorithms or artificial intelligence components to render key portions of a service. For example, in the CY 2018 OPPS final rule (82 FR 59284), we discussed the fractional flow reserve computed tomography (FFRCT) service. We noted that that the service, which we considered to be separate and distinct from the original coronary computed tomography angiography service is not an image processing service but rather, the diagnostic output from the FFRCT reports functional flow values that can only be obtained using FFRCT. We found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other new forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PFS payment methodology. Accordingly, we established contractor pricing for the service and have continued to gather information from stakeholders on payment that appropriately reflects resource cost for this service under the PFS payment methodology for the codes below. Our recent reviews of the overall cost for the service and specifically for the analysis component of the service related to the analysis services listed below have shown the costs to be similar, to the costs reflected in payment under the CY 2021 OPPS final rule for CPT code 0503T (analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model).

We look forward to continuing to seek out new data sources and ongoing conversations with stakeholders to help in updating the PE methodology and the underlying data to better reflect such services. In the meantime, we are finalizing payment based on contractor pricing for CPT code 92229.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 92227 and 92228 as proposed and are finalizing contractor pricing for CPT code 92229 as detailed above.

(37) Auditory Evoked Potentials (CPT Codes 92584, 92650, 92651, 92652, and 92653)

CPT codes 92585 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive*) and 92586 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited*) were identified through a RAW requested screen of CMS/Other Source codes with 2017 Medicare utilization over 30,000. Since these codes were last valued, audiologists, the primary reporter of these services, can now report Medicare services independently. As a result, the audiologist work for these services is moving from PE to work.

To better describe tests of auditory function, the CPT created CPT code 92584 (*Electrocochleography*) and replaced CPT codes 92585 and 92586 with four new services. We proposed the RUC-recommended work RVUs of 1.00 for CPT code 92584, 1.00 for CPT code 92651 (*Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report*), 1.50 for CPT code 92652 (*Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report*), and 1.05 for CPT code 92653 (*Auditory evoked potentials; neurodiagnostic, with interpretation and report*). CPT code 92650 (*Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis*) is a screening service and is not payable by Medicare. Therefore, we did not propose a valuation for this code; however, we noted we will display RUC-recommended values associated with the code.

We proposed the RUC-recommended direct PE inputs for this code family without refinement.

We received public comments on the Auditory Evoked Potentials codes (CPT codes 92584, 92650, 92651, 92652, and 92653). The following is a summary of the comments we received and our responses.

Comment: Commenters uniformly expressed support for our proposal to accept the RUC-recommended work RVUs and direct PE inputs for CPT codes 92584, 92651, 92652, and 92653.

Response: We appreciate the commenters' support.

Comment: Commenters requested that CMS publish the RUC-recommended work, PE, and malpractice RVUs for CPT code 92650. CPT code 92650 is a key component of universal newborn hearing screening programs that are widely furnished across the country. As such, it is critical for CMS to display the total RVUs—to include the RUC's recommended work, PE, and MP RVUs—to allow state Medicaid agencies, newborn hearing programs, and commercial insurers to appropriately value 92650.

Response: We did not propose values for CPT code 92650 because it is not a covered Medicare service. However, we will post the RUC-recommended RVUs for this code.

Comment: Commenters also noted a discrepancy between Addendum B—which indicates 92650 is an active code (status indicator ''A'')—and the narrative in the proposed rule, which states that 92650 is a screening code and not payable by Medicare.

Response: We acknowledge the error and have corrected it in Addendum B.

Comment: Commenters requested that CMS create a professional and technical

component (PC/TC) split for CPT codes 92650, 92651, 92652, and 92653. Other audiology codes including CPT codes 92585 and 92586, which are being replaced by 92650–92651, also included the PC/TC split.

Response: We appreciate commenters' suggestion that we create PC/TC splits for CPT codes 92650, 92651, 92652, and 92653. When we reviewed the code descriptors and the RUC recommendations for the codes, we noted that the direct PE for the new codes no longer includes clinical staff time. We also noted that the now deleted codes included clinical staff time that was assigned to an audiologist. We understood that the new codes represented changes to the service; audiologists were now able to bill independently for the work. During our review, we did not consider a PC/TC split and were surprised by the commenters' suggestion. Looking forward, we may consider this suggestion during future rulemaking.

After considering the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Auditory Evoked Potentials family as proposed.

(38) Vestibular Evoked Myogenic Potential Testing (CPT Codes 92517, 92518, and 92519)

In response to a 2017 RAW request, AMA staff compiled a list of CMS/Other codes with Medicare Utilization of 30,000 or more. CPT code 92585 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive*) was identified as one of the codes. In 2018, the AMA/RUC referred CPT code 92585 and its family member CPT code 92586 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited*) to the February 2019 CPT Editorial Panel meeting to clarify code descriptors and define the terms ''limited'' and ''comprehensive'' auditory evoked potentials.

During the discussion of CPT codes 92585 and 92586 at the February 2019 CPT Editorial Panel meeting, specialty societies introduced a new procedure, Vestibular Evoked Myogenic Potential (VEMP), and suggested new coding. As a result, the CPT Editorial Panel created 3 new codes: CPT code 92517 (*Vestibular evoked myogenic potential testing, with interpretation and report; cervical (cVEMP)*); CPT code 92518 (*Vestibular evoked myogenic potential testing, with interpretation and report; ocular (oVEMP)*); and CPT code 92519 (*Vestibular evoked myogenic potential testing, with interpretation and report; cervical and ocular*). The RUC reviewed the three codes at its April 2019 meeting.

We proposed the RUC-recommended work RVU of 0.80 for CPT codes 92517 and 92518. For CPT code 92519, we proposed the RUC-recommended work RVU of 1.20. We also proposed the RUC-recommended direct PE inputs without refinement for these three VEMP codes.

We received public comments on the Vestibular Evoked Myogenic Potential Testing family (CPT codes 92517, 92518, and 92519). The following is a summary of the comments we received and our responses.

Comment: Commenters wrote to express support for our proposal to accept the RUC-recommended work RVUs.

Response: We appreciate the support of commenters.

Comment: Commenters requested that CMS create a professional and technical component (PC/TC) split for the new codes. These commenters noted that audiologists who perform services in a facility setting require a mechanism to accurately report the professional component for their services. Commenters cited other vestibular testing codes such as CPT codes 92548 and 92549 that have a PC/TC split.

Response: We appreciate commenters' interest in the creation of a PC/TC split for CPT codes 92517, 92518, and 92519. When we reviewed the code descriptors and the RUC recommendations, we noted that the direct PE for this set of new codes did not include clinical staff time. As a result, we did not consider a PC/TC split. However, as a result of the commenters' suggestion, we may consider the PC/TC split a topic of future rulemaking.

After consideration of public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Vestibular Evoked Myogenic Potential Testing family as proposed.

(39) Complete Electrocardiogram (CPT Codes 93000, 93005, and 93010)

In the CY 2019 PFS final rule (83 FR 59452), CPT code 93000 was nominated for review under the potentially misvalued code initiative. The RUC reviewed these services at the April 2019 meeting where the specialty societies explained that the family of electrocardiogram (ECG) codes were relatively unique in that CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*) is the global service which is billed in the hospital setting, CPT code 93005 (*Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report*) is the technical component and CPT code 93010 is the professional component.

We proposed the RUC-recommended work RVU of 0.17, which is the current value for both codes, for CPT codes 93000 and 93010. CPT code 93005 is a PE only technical component code, and we proposed to maintain the current work RVU of 0.00.

For the direct PE inputs, we proposed the RUC-recommended values without refinement.

We did not receive public comments on this code family, and therefore, we are finalizing as proposed.

(40) External Extended ECG Monitoring (CPT Codes 93224, 93225, 93226, 93227, 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248)

In September 2019, the CPT Editorial Panel replaced four Category III codes with 8 new Category I codes to report external electrocardiographic (ECG) recording by continuous rhythm recording and storage for periods longer than 48 hours. The existing Holter monitor codes (CPT codes 93224 through 93227) that include up to 48 hours of continuous recording were also reviewed as part of this family of services at the January 2020 RUC meeting.

We proposed the RUC-recommended work RVU for all 12 codes in the family. We proposed a work RVU of 0.39 for CPT codes 93224 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional*) and 93227 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional*); a work RVU of 0.50 for CPT codes 93241 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*) and 93244 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation*); and a work RVU of 0.55 for CPT codes 93245 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*) and 93248 (*External electrocardiographic recording for more*

than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation).

The other six codes in the family are technical component codes that do not have a work RVU; we proposed a work RVU of 0.00 for CPT codes 93225 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)*), 93226 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report*), 93242 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), 93246 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), and 93247 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*).

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Perform procedure/service—NOT directly related to physician work time'' (CA021) activity for CPT codes 93241, 93243, 93245, and 93247. We proposed to reduce the clinical labor time by 5 minutes for each code as the description of the tasks taking place in the recommended materials includes activities that are considered to be indirect PE under our methodology. The recommended materials stated that ''incoming patch deliveries are sorted and distributed to work queues. The return box is opened, diary book removed, top housing is removed using a custom tool to expose USB connection, and device is plugged in to extract serial number and diagnostic logs.'' These unboxing and filing activities are classified as administrative expenses under our PE methodology, and therefore, do not constitute clinical labor as a direct expense. We proposed to remove 5 minutes from the clinical labor to reflect these activities, which are indirect as opposed to direct costs. We also proposed to refine the equipment time for the desktop computer (ED021) to reflect these changes in the clinical labor time.

We noted an inconsistency in the RUC-recommended direct PE inputs for CPT codes 93241 and 93245. Both of these codes are the ''global component'' for their respective group of codes, such that the direct costs for CPT codes 93242–93244 must sum up to the direct cost of CPT code 93241 and the direct costs for CPT codes 93246 through 93248 must sum up to the direct cost of CPT code 93245. However, CPT codes 93241 and 93245 each contained 2 pairs of non-sterile gloves (SB022) whereas their constituent technical component codes (93242 and 93246 respectively) only contained a single pair of non-sterile gloves. Therefore, we proposed to refine the quantity of the non-sterile gloves down to 1 pair for CPT codes 93241 and 93245 to correct this inconsistency. We noted we also considered increasing the quantity of the gloves to 2 as in CPT codes 93224 through 93227. However, we believed that only 1 pair of gloves would typically be needed to attach the ECGs, as the patient does not return to have the ECGs removed in CPT codes 93241 through 93248 as opposed to CPT codes 93224 through 93227 where the patient does return for ECG removal.

We proposed the RUC-recommended equipment time of 1,474 minutes for the Holter monitor (EQ127) equipment included in CPT codes 93224 and 93226, based on an equipment time of 34 minutes during the procedure along with 1,440 minutes (24 hours) of equipment time thereafter. We noted that an external stakeholder wrote to request that the number of minutes of equipment time for the Holter monitor be increased from 1,440 minutes (24 hours) to 2,160 minutes (36 hours) to reflect the average length of equipment time. The stakeholder wrote that the 24-hour and 48-hour test were each performed approximately 50 percent of the time and stated that the most accurate number of equipment minutes would be the average time. The RUC disagreed with the stakeholder's request in its review because it concluded that there was insufficient evidence to warrant a change from the current 24 hours of equipment time; the RUC-recommended equipment time for the Holter monitor was based on the typical rather than the average service. We proposed the RUC-recommended equipment time of 1,474 minutes because our PE methodology is indeed based on the typical case, specifically what would be typical and reasonable and necessary for the procedure in question. Although we appreciated the feedback from the stakeholder, our previously finalized PE methodology establishes pricing based on the typical case. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

The recommendations for this family of codes contain one new supply item, the ''extended external ECG patch, medical magnetic tape recorder'' (SD339). We did not receive a traditional invoice to establish a price for this supply item, instead receiving pricing information from two sources: A weighted median of claims data with the cost of the other direct PE inputs removed, and a top-down approach calculating the cost of the supply per service based on summing the total costs of the health care provider and dividing by the total number of tests furnished. The former methodology yielded a supply price of approximately $440 while the latter methodology produced an estimated supply price of $416.85. Stakeholders also submitted a series of invoices from the clinical study marketplace with a price of $595. Although we are appreciative of the data provided by the stakeholder, we require an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item. Although we are aware of the unusual circumstances surrounding the ''extended external ECG patch, medical magnetic tape recorder'' in terms of how it uploads data to the health care provider, we cannot establish supply pricing based on an analysis of claims data and in absence of a representative invoice.

Therefore, we proposed to employ a crosswalk to an existing supply for use as a proxy price until we have an invoice to use for the ''extended external ECG patch, medical magnetic tape recorder'' item. We proposed to use the ''kit, percutaneous neuro test stimulation'' (SA022) supply as our proxy item at a price of $413.24. Although this kit is not clinically similar to the extended external ECG patch, we believe that it is the closest match from a pricing perspective to employ as a proxy until we are able to arrive at an invoice that is representative of commercial market pricing. We welcomed the submission of invoices or other additional information for use in pricing the ''extended external ECG patch, medical magnetic tape recorder'' supply.

We received public comments on the codes in the External Extended ECG Monitoring family. The following is a

summary of the comments we received and our responses.

Comment: Several commenters supported the proposal of the RUC-recommended work RVUs for all of the codes in the External Extended ECG Monitoring family.

Response: We appreciate the support for our proposals from the commenters.

Comment: One commenter supported the proposal to refine the quantity of the non-sterile gloves down to 1 pair for CPT codes 93241 and 93245 to correct an inconsistency in the RUC recommendations. The commenter agreed that this corrected a summing error.

Response: We appreciate the support for our proposals from the commenter.

Comment: Several commenters disagreed with the proposal to reduce the clinical labor time for the ''Perform procedure/service—NOT directly related to physician work time'' (CA021) activity for CPT codes 93241, 93243, 93245, and 93247 by 5 minutes. Commenters stated that delivery and assignment tasks may be fair to characterize as administrative, but accessing the device, connecting it, and downloading data is more akin to the CA032 activity code (''Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.'') when clinical data is put into the system. Commenters recommended that CMS reduce clinical staff time by 1 minute, not 5, to account for the delivery sorting, distribution, and box opening.

Response: We continue to disagree with the commenters and maintain that the proposed reduction of 5 minutes of clinical labor time is warranted as the activities listed by commenters are forms of indirect PE. Data entry tasks such as connecting a device and downloading data are typically considered to be forms of indirect PE unless they are directly allocable to a particular patient for a particular service. We do not agree that the suggested comparison to the CA032 activity code would be accurate for these services, as the CA032 activity code requires the use of a PACS workstation, which is not present in any of these CPT codes.

Comment: Several commenters disagreed with CMS' position regarding equipment time for the wearable holter monitor (EQ127) device. Commenters stated that they had presented evidence to the RUC demonstrating that about half of the services described by CPT code 93226 involve 24 hours of monitoring and about half are for 48 hours; based on this, the commenter suggested that the ''typical'' service was 36 hours—the average of 24 and 48 hours. The commenter stated that the RUC and CMS did not agree as both take the view that the ''typical'' service requires a binary choice between 24 and 48 hours. The commenter stated that they believe a more accurate methodology for valuing equipment time is to look to objective and quantifiable data such as the average number of hours of use rather than the ''either/or'' methodology which inevitably undervalues approximately 50 percent of tests.

Response: Although we appreciated the feedback from the stakeholder, as we stated in the proposed rule, our previously finalized PE methodology establishes pricing based on the typical case and not the average result. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

Comment: We received many comments regarding our proposal to price the ''extended external ECG patch, medical magnetic tape recorder'' (SD339) supply via a proxy item at a price of $413.24. Several commenters supported the proposed proxy pricing, stating that because the independent diagnostic testing facilities that furnish the extended ECG services are also the manufacturers of the devices, there are no invoices that reflect the sale or purchase of this supply item or the related software required to scan and analyze the extended ECG data recorded on this patch. These commenters stated that CMS should finalize the pricing as proposed and advised caution when reviewing pricing for what appear to be extended ECG system components, and to assess whether the invoiced items represent the supplies and equipment required to furnish the typical case of the service described by the new codes.

Other commenters strongly disagreed with the proposed proxy pricing for the SD339 supply. Commenters stated that they were alarmed that CMS's proposal would result in payment rates far in excess of the costs incurred when performing these services in direct violation of CMS's stated principles for reimbursement rates. One commenter stated that CMS proposed rates at more than four times where they should be valued under its standard PE cost accounting methodology. Several commenters stated that the SD339 patch was available for purchase at roughly $100 to $120 if bought in bulk quantities, which the commenters stated made sense because these ECG patches are not high tech equipment. Several commenters were concerned that CMS had not followed its traditional methodology for supply pricing by valuing the SD339 patch without receiving an invoice submission. Commenters stated that the proposed proxy pricing incorporated the research and development costs associated with developing the patch, which are typically indirect costs under the PE methodology, and CMS was therefore double-paying for these expenses by including them as a direct cost. Commenters also raised concerns that providers of these services might be able to make up to $200 per patient through the sale of discounted patch kits by profiting from the spread between the CMS payment and the much lower cost of the product. Commenters stated that this could create an incentive for significant overutilization of these services. One commenter submitted a lengthy report suggesting that CMS reject the proxy supply input approach and value the external ECG patch not as a supply but as a form of reusable equipment. This commenter submitted a series of invoices to support their contention that the external ECG patch would be more accurately priced as a reusable form of equipment at a much lower reimbursement rate.

One commenter who supported the proposed proxy pricing later submitted a second comment responding to the commenters' criticisms of the proposal. This commenter stated that the devices and systems described by the invoices presented by other commenters were not consistent with the diagnostic system typically used to furnish the services described by these new codes. The commenter stated that there were systemic differences between the extended external ECG patch and the items described by the invoices referenced by other commenters. The commenter reiterated that the proposed proxy price should be finalized as it is supported by peer-reviewed clinical evidence from the specialty societies.

Response: Given the conflicting information and assertions provided by commenters, we are unable to identify accurate national pricing for the ''extended external ECG patch, medical magnetic tape recorder'' (SD339) supply. To allow additional time to receive more pricing information, we are finalizing contractor pricing for CY 2021 for the four codes that include this supply input (CPT codes 93241, 93243, 93245, and 93247). We will retain the SD339 supply in our pricing database while removing the proxy price pending additional information. We welcome the

submission of additional invoices or other pricing information to assist us to determine the most accurate values for these services.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 93224, 93225, 93226, 93227, 93242, 93244, 93246, and 93248. We are finalizing contractor pricing for CPT codes 93241, 93243, 93245, and 93247 as detailed above.

(41) Complete Transthoracic Echocardiography (TTE) With Doppler (CPT Code 93306)

In the CY 2019 PFS final rule (83 FR 59500), a submitter nominated CPT code 93306 (*Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography*) as potentially misvalued, citing GAO, MedPAC, and Urban Institute reports that suggest the work RVUs are overstated. Although the code was most recently surveyed in 2016, the specialty societies and the RUC stated that there has been a change in the technique and technology used to perform the procedure, so they resurveyed the code. The RUC recommended decreasing the work RVU from 1.50 to 1.46 and we proposed this value.

Although we proposed the RUC-recommended direct PE inputs without refinement, we noted that the RUC's recommendation included both 25 mL and 50 mL of ultrasound transmission gel. We proposed a supply quantity of 25 mL and sought clarification on the correct amount.

We received public comments on the proposed valuation of CPT code 93306. The following is a summary of the comments we received and our responses.

Comment: A few commenters were supportive of our proposals for the work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenters.

Comment: A few commenters confirmed that the correct supply quantity of the ultrasound transmission get was 25 mL.

Response: We appreciate the clarification and are finalizing the ultrasound transmission gel supply quantity as proposed.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for CPT code 93306 as proposed.

(42) Pacing Heart Stimulation (CPT Code 93623)

Review of CPT code 93623 (*Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)*), was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 30,000 claims in a year. This service is to create an arrhythmia by an intravenous drug infusion and it is an add-on code with 60 minutes of total time and a current work RVU of 2.85.

The RUC recommended the 25th percentile survey value of 2.04 work RVUs and 20 minutes of intraservice time.

The revision of CPT code 93623 physician's time adjusting from the current 60 minutes to 20 minutes is a significant change. We noted that we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we noted that we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 93623, we believed that it would be more accurate to propose a work RVU of 0.98 based on CPT code 76810 (*Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation (list separately in addition to code for primary procedure)*) with 20 minutes of intraservice time. We proposed a work RVU of 0.98 with 20 minutes of intraservice time for CPT code 93623.

This CPT code is a facility-only service and has no direct PE inputs.

We received public comments on the Pacing Heart Stimulation CPT code 93623. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with our selection of CPT code 76810 as an equivalent comparator to CPT code 93623 in regard to the work RVUs and the number of total minutes derived from the 'CMS Other' category listed in CMS's physician time file. Commenters stated that the nature of the type of work and intensity for the service described by CPT code 76810 are vastly different from Pacing Heart Stimulation. The commenters strongly suggested that CMS accept the 25th percentile work RVU of 2.04 from their recent survey of 46 cardiologists.

Response: We continue to believe that CPT code 76810 is a valid reference for purposes of valuing CPT code 93623, and that the physician time change from the current 60 minutes to 20 minutes indicates a reduction in work RVUs. As we have discussed in previous rules, we continue to believe that our use of the existing time values as a point of comparison is critical to the integrity of the current relative value system and we do not accept the characterizing of a time source as ''CMS-Other'' as being less valid. As for CPT code 76810 having only total time instead of intraservice time, for add-on codes, total time is almost always the equivalent of intraservice time, and both of these add-on codes have 20 minutes of total time. We do not regard the 20 minutes of physician time assigned to CPT code 76810 to be any different from the 20 minutes of physician time with CPT code 93623. While the clinical nature of the work for CPT code 76810 is different from the clinical nature of the work for CPT code 93623, our review of the assigned RVU is based on a comparison of the physician times and intensity assigned to each code, which are the same.

After consideration of the public comments, we are finalizing the work and time values for CPT code 93623 as proposed.

(43) Intracardiac Echocardiography (ECG) (CPT Code 93662)

The review of CPT code 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure*), was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 10,000 claims in a year that had an increase in volume by 100 percent between the 2012 to 2017. This procedure has since changed from its last review, in its reduced use of fluoroscopy, now replaced with ultrasound that create arrhythmia mapping systems with intracardiac echo images processed to produce 3-dimensional electroanatomical maps. The physician can now visualize better and have more accurate details for more effective catheter ablation for a wide range of arrhythmias. CPT code 93662 currently has a work RVU of 2.80 with 5 minutes of preservice evaluation time, 55 minutes of intraservice time, 10 minutes of immediate postservice time, and 70 minutes of total time.

The survey resulted in a median intraservice time of 25 minutes, a significant shift from the current intraservice time of 55 minutes. The RUC recommended a work RVU of 2.53 and 25 minutes of intraservice time for add-on CPT code 93662. We noted that we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believed that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. CPT code 92979 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (list separately in addition to code for primary procedure)*), with 1.44 work RVUs and 25 minutes of intraservice time, is a good equivalent comparator code in light of the significant physician time reduction from 55 minutes. A similarly proportioned reduction of physician intraservice time from the current 55 minutes to the surveyed 25 minutes, if applied to the current work RVU would result in a value much lower than our reference CPT code 92979's work RVU, so we proposed a work RVU of 1.44 and 25 minutes of intraservice time for add-on CPT code 93662.

This CPT code is a facility only service and has no direct PE inputs.

We received public comments on the service of Intracardiac Echocardiography (ECG) CPT code 93662. The following is a summary of the comments we received and our responses.

Comment: The AMA RUC disagreed with our selection of CPT code 92979 as an equivalent comparator code to CPT code 93662 because of ECG's higher technical nature, and its use of anesthesia which supports a higher intensity and a difference in the nature of the work. As in their AMA RUC recommendation, they referenced their selection of CPT code 34713 (*Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral (List separately in addition to code for primary procedure)*) with a work RVU of 2.50 and an intraservice time of 20 minutes. The commenters strongly suggested that CMS accept their comparison code and the 25th percentile work RVU of 2.53 from their recent survey of 42 cardiologists.

Response: We consider CMS' selection of CPT code 92979 to be a more appropriate comparator to value CPT code 93662, than the AMA RUC's selection of comparator CPT code 34713, and believe that the physician time change from the current 55 minutes to 25 minutes indicates a reduction in work RVUs of greater than 0.27. We also do not agree with the AMA RUC that the increase in ECG's work intensity supports the AMA RUC recommended 2.53 work RVUs (90% of the current value). The substantial reduction in physician time (45%) and increase in work intensity, is not reflected in the AMA RUC-recommended reduction of work RVUs. CPT code 92979's intraservice time of 25 minutes and 1.44 work RVUs is a better equivalent that reflects the halving on the physician's current time and we do not believe that the work intensity has substantial change enough to justify the AMA RUC's recommended work value. We note that CPT code 93662's work value is for the professional component (26) that is set in the fee schedule and that CPT code 93622's technical component and global are also add-on codes and are carrier-priced, meaning that if the health care provider performs both components, their final payment will be more than the work RVUs finalized here.

After consideration of the public comments, we are finalizing a work RVU of 1.44 with 25 minutes of intraservice time for CPT code 93662 as proposed.

(44) Ventricular Assist Device (VAD) Interrogation (CPT Code 93750)

The review of CPT code 93750, (*Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report*) was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 10,000 claims in a year and had had an increased in volume by 100 percent between the 2012 to 2017. CPT code 93750 currently has a work RVU of 0.92 with 30 minutes of intraservice time.

For physician times, the societies' survey for CPT code 93750 yielded 6 minutes preservice time, 10 minutes intraservice time, 7 minutes immediate post-service time, and 23 minutes of total time. The 25th percentile surveyed work RVU was 0.96. The RUC compared the survey code to CPT code 78598 (*Quantitative differential pulmonary perfusion and ventilation (e.g., aerosol or gas), including imaging when performed*) (0.85 work RVU and 5 minutes of preservice time, 10 minutes of intraservice time, 9 minutes of immediate postservice time, and total time of 24 minutes). The RUC recommended crosswalking the work RVU of 0.85 from CPT code 78598 to 93750.

CPT code 93289 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements*), with 0.75 work RVUs and 5 minutes of preservice time, 10 minutes of intraservice time, 8.5 minutes of immediate postservice time, and total time of 23.5 minutes, we noted we believe is a more precise comparator code. CPT code 93289's intraservice times, pre and post times, and total times are almost identical to CPT code 93750's survey times; therefore, we proposed a work RVU of 0.75 and 23 minutes of total time for CPT code 93750.

The PE Subcommittee corrected the equipment times based on the formulas as provided by CMS. In addition, the PE Subcommittee changed the clinical staff type for direct labor item ID CA013 Prepare Room, Equipment and Supplies, from an RN to the RN/LPN/MTA blend and the direct equipment item ID EQ168 light, exam was removed from CPT code 93750. We proposed to accept the RUC-recommended direct PE inputs.

We received public comments on the Ventricular Assist Device (VAD) Interrogation CPT code 93750. The following is a summary of the comments we received and our responses.

Comment: The AMA RUC surveyed CPT code 93750 and initially reviewed their surveyed 25th percentile recommendation of 0.96 work RVUs for this code, finding it to be overestimated, since the current work RVU value is 0.92 for the current 30 minutes of physician time. Instead, they selected CPT code 78598 as a comparator code with a work RVU of 0.85. Commenters disagreed with our selection of CPT code 93289 with a work RVU of 0.75 as inappropriately low, but they noted that they had originally reviewed CPT code

93289 only to abandon this code on the basis that it did not involve device programming.

Response: We disagree with commenters that our selection of comparator CPT code 93289 is inappropriate. The reduction in time from 30 minutes to 23 minutes suggests that the work RVUs should be decreasing, and the survey's 25th percentile reflects an increase. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we continue to believe that, since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs; and that CPT code 93289 is a more appropriate comparator to CPT code 93750.

After consideration of the public comments, we are finalizing a work RVU of 0.75 with a total time of 23 minutes for CPT code 93750, as proposed.

(45) Spirometry (CPT Codes 94010 and 94060)

CPT code 94010 (*spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and CPT code 94060 (*Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration*) were identified as part of a Relativity Assessment Workgroup (RAW) review of action plans on the status of services that were RUC referrals to develop CPT Assistant articles. These codes were recommended to be surveyed.

We proposed the RUC-recommended work RVU of 0.17 for CPT code 94010 (*spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and the RUC-recommended work RVU of 0.22 for CPT code 94060 (*Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration*). We proposed the RUC-recommended direct PE inputs for this code family without refinements.

We did not receive public comments on this code family, and are finalizing as proposed.

(46) Exercise Test for Bronchospasm (CPT Codes 94619, 94617, 94618, and 94621)

In 2018, the CPT Editorial Panel created CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*), and CPT code 94618 (*Pulmonary stress testing (e.g., 6-minute walk test), including measurement of heart rate, oximetry, and oxygen titration, when performed*) from the now deleted CPT code 94620 (*Pulmonary stress testing; simple (e.g., 6-minute walk test, prolonged exercise test for bronchospasm with pre- and post-spirometry and oximetry)*), and revised CPT code 94621 (*Cardiopulmonary exercise testing, including measurements of minute ventilation, co2 production, o2 uptake, and electrocardiographic recordings*) to better describe the specialty's pulmonary exercise test. Shortly after the creation and revision of these codes, the specialty society became aware of some health care providers performing CPT code 94617 without ECG monitoring, so to more accurately account for this work without the ECG monitoring, the CPT Editorial Panel proposed to establish CPT code 94619 with the descriptor, (*Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)*). For the October 2019 RUC meeting, the specialty societies surveyed CPT code 94619, and included a request to reaffirm the values of the rest of the codes in the code family.

For CPT code 94619, the surveyed physician time yielded 5 minutes of preservice time, 9 minutes of intraservice time, followed by 10 minutes of immediate post-service time, for a total time of 24 minutes. This distribution of physician times is of course very similar to the times for CPT code 94617, total time of 26 minutes, except without the task of including an electrocardiographic recording. The RUC recommended the survey's median work RVU of 0.49 for CPT code 94619.

We proposed the RUC's recommendation of a work RVU of 0.49 and a total physician time of 24 minutes for CPT code 94619.

This CPT family of codes that includes CPT code 94619, are CPT codes 94617, 94618, and 94621 and there are no changes to their physician service times, no change to their descriptors, nor their work RVUs, and remain as they currently are. The specialty societies reaffirmed these current valuations and we proposed to accept them without change.

We proposed the RUC-recommended PE changes without refinement.

We did not receive public comments on this provision, and are finalizing as proposed.

(47) Evaluation of Wheezing (CPT Codes 94640, 94667, 94668, and 94669)

At the April 2019 RUC meeting, four PE only CPT codes from the Evaluation of Wheezing code family were reviewed. The codes included CPT codes 94640 (*Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device*), 94667 (*Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation*), 94668 (*Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lunch function; subsequent*), and 94669 (*Mechanical chest wall oscillation to facilitate lung function, per session*).

We proposed the RUC-recommended direct PE inputs for the four PE only codes. The RUC did not recommend work RVUs and we proposed to maintain the current work RVU of 0.00 for all four codes.

We did not receive public comments on this code family, and are finalizing as proposed.

(48) Exhaled Nitric Oxide Measurement (CPT Code 95012)

In January 2019, the RAW reviewed services with 2017 Medicare utilization of 10,000 or more that had increased by at least 100 percent from 2012 through 2017. The RUC recommended that CPT code 95012 (*Nitric oxide expired gas determination*) be surveyed for the April 2019 meeting. We proposed the direct PE inputs for CPT code 95012 without refinement. CPT code 95012 is a PE-only code with no work RVU, and we proposed to maintain the current work RVU of 0.00.

We did not receive public comments on this code family and are finalizing as proposed.

(49) Acupuncture Services (CPT Codes 97810, 97811, 97813, and 97814)

The CPT Editorial Panel created two new codes and two new add-on codes in 2004 to describe the appropriate time or additional time and levels of service that can be performed using acupuncture and electroacupuncture,

acupuncture therapy with electrical stimulation. These codes were designated as noncovered services since Medicare did not reimburse for acupuncture services at the time. In January 2020, we issued a decision memo stating that Medicare will cover acupuncture for chronic low back pain under section 1862(a)(1)(A) of the Act (CAG–00452N). This was reflected in the April 2020 PFS Quarterly Update which changed CPT codes 97810 through 97814 to active payment status (CMS Change Request 11661). Because we had never conducted a review of these four acupuncture codes, the CY 2020 payment rate consisted of the work RVUs recommended by the RUC in 2004.

For CY 2021, we proposed to establish work RVUs for these four acupuncture codes based on a pair of crosswalks to two recently reviewed codes in the Dry Needling family. We proposed a work RVU of 0.48 for CPT codes 97810 (*Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*) and 97813 (*Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*) based on a crosswalk to CPT code 20561 (*Needle insertion(s) without injection(s); 3 or more muscles*). We proposed a work RVU of 0.32 for CPT codes 97811 (*Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)*) and 97814 (*Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)*) based on a crosswalk to CPT code 20560 (*Needle insertion(s) without injection(s); 1 or 2 muscle(s)*).

CPT codes 20560 and 20561 are clinically similar services associated with dry needling that were reviewed last year for CY 2020. We finalized work RVUs of 0.32 and 0.48 respectively for these two codes following our review of their associated RUC recommendations, while noting that dry needling services were non-covered by Medicare unless otherwise specified through a national coverage determination (NCD) (84 FR 62722 through 62724). Like the acupuncture codes, CPT codes 20560 and 20561 were updated to active payment status in the April 2020 PFS Quarterly Update to reflect the Medicare coverage of acupuncture for chronic low back pain. We noted that CPT codes 97810 and 97813 share the identical work time values with CPT code 20561, and that CPT codes 97811 and 97814 differ from CPT code 20560 by only 1 minute of work time, 15 minutes as compared to 16 minutes. Although we did not imply that codes with similar work times must equate to a one-to-one or linear relationship in the valuation of work RVUs, we believed that, since the two components of work are time and intensity, clinically related services with similar intensities and work times should, generally speaking, be valued similarly. Due to the similar clinical nature of these services and their nearly identical work times, we believed that it is more accurate to propose crosswalking CPT codes 97810 through 97814 to the work RVUs of the Dry Needling codes, which were finalized last year, as opposed to proposing work RVUs from 2004, which were never reviewed by CMS.

The RUC did not make any recommendations and we did not propose any changes to the direct PE inputs for CPT codes 97810 through 97814.

We received public comments on the codes in the Acupuncture Services family. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed work RVUs assigned to the acupuncture codes and appreciated CMS' recent coverage determination. The commenters stated that it is important for CMS to provide coverage and adequate reimbursement to a broad array of services that provide non-opioid pain management alternatives.

Response: We appreciate the support for our proposals from the commenters.

Comment: Many commenters were supportive of the Medicare decision to provide coverage for acupuncture services but disagreed with the proposed valuation crosswalk to two recently reviewed codes in the Dry Needling family. Commenters stated that the dry needling services were not clinically similar to the acupuncture codes as CMS had claimed in the proposed rule, as the dry needling codes do not reflect the training or expertise required to perform an acupuncture treatment. Commenters stated that acupuncture is more physically and mentally intensive than inserting a dry needle into a tender muscle. Commenters stated that the higher skill and knowledge set that is required to perform acupuncture therapy is evidenced in the licensure requirements to perform these services, whereas there are no standardized training curriculums or accreditation programs for dry needling. Commenters stated that the current acupuncture therapy codes are specifically intended to include pre- and post-service intervention assessment/evaluation, as per the CPT guidelines, which is lacking in the dry needling codes. Many commenters stated that if Medicare rates are reduced for acupuncture services then providers of acupuncture services will not be able to afford to treat Medicare beneficiaries and this would create additional barriers to care.

Response: We appreciate the detailed feedback from the commenters detailing the differences between acupuncture and dry needling services. After reviewing the comments, we agree that there are significant differences between these services and it would not be appropriate to use the proposed crosswalk for valuation. Therefore, we are not finalizing our proposal to establish work RVUs for these four acupuncture codes based crosswalks to CPT codes 20560 and 20561. We are instead finalizing the current CY 2020 work RVUs of 0.60 for CPT code 97810, 0.50 for CPT code 97811, 0.65 for CPT code 97813, and 0.55 for CPT code 97814. As this valuation is based on a RUC review that took place in 2005, we welcome the prospect of an updated formal review or other new information regarding the valuation of these services for potential future rulemaking.

(50) Interim Final Rule With Comment Period for Coding and Payment for Personal Protective Equipment (PPE) (CPT Code 99072)

a. Background

Following the publication of the CY 2021 PFS proposed rule, the CPT Editorial Panel approved the creation of CPT code 99072 (*Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease*). During the comment period for the proposed rule, stakeholders contacted CMS and stated that practices have incurred significant costs of maintaining safe offices, particularly in implementing specific infection control measures related to screening patients, purchasing personal protective equipment (PPE), and implementing office redesign measures to ensure social distancing. Stakeholders requested that CMS immediately consider implementation of relative values and payment (outside of budget neutrality) for the newly created CPT code 99072 in recognition of these costs.

Stakeholders submitted recommended direct PE inputs associated with CPT code 99072 designed to capture the additional supplies, materials, and clinical staff time over and above the PE inputs included in an office visit or other nonfacility service(s) when the office visit or other non-facility service(s) are rendered during a public health emergency (PHE). Stakeholders submitted more than 500 invoices associated with PPE supplies and requested that CMS use them to update their pricing, as well as requested that N95 masks should be added to the direct PE supply list. Stakeholders stated that payment for these additional costs should be fully funded and not be subject to budget neutrality, and that CMS could use remaining money from the CARES Act funding to pay physicians for these costs and/or recognize the decreased expenditures during the early months of the pandemic to waive budget neutrality. Stakeholders also stated that CMS should review the utilization assumptions for equipment due to decreased practice capacity during the PHE for COVID–19 and that any modifications to the equipment utilization during the PHE should not be subject to budget neutrality.

b. Interim Final Policy

We appreciate the submission of this additional information regarding CPT code 99072, especially the large number of invoice submissions for use in updating the pricing of PPE supplies. We share in the concerns of the stakeholders regarding the additional costs borne by providers during the public health emergency. After reviewing the information provided by the stakeholders, we are finalizing CPT code 99072 as a bundled service on an interim basis. We believe that use of these additional forms of PPE would be inherent to the furnishing of separately paid services under these practitioner/patient interactions. We agree with the stakeholders that there have been additional costs for providers as part of the PHE for COVID–19; however payment for the services as described under CPT code 99072 are always bundled into payment for other services and payment for them is subsumed by the payment for the services to which they are incident.

In recognition of the increased market-based costs for certain types of PPE, we are finalizing on an interim basis several supply pricing increases using the invoices submitted along with CPT code 99072. We did not previously include the N95 mask in our supply database and we are finalizing on an interim basis its addition under supply code SD344 at the median price of $2.36 based on 94 submitted invoices. We are also finalizing on an interim basis an increase in the price of the surgical mask (SB033) supply to the median price of $0.43 based on 259 submitted invoices and an increase in the price of the surgical mask with face shield (SB034) supply to the median price of $3.40 based on 49 submitted invoices. We are using the median price as opposed to the average price of the submitted invoices as the median was more typical of market-based pricing and avoided the effect of outlier prices. The increased cost associated with these forms of PPE will be reflected in payment for services that include these supply inputs.

We also received additional invoices associated with non-sterile gloves (SB022), nitrile gloves (SB023), patient gowns (SB026), and sterile surgical gowns (SB028). We are not finalizing changes in the prices of these supplies at this time due to concerns that we had regarding the data on the submitted invoices. The non-sterile gloves and nitrile gloves contained median prices which were significantly lower than their CY 2021 prices, $0.05 as compared to $0.25 for the non-sterile gloves and $0.06 as compared to $1.01 for the nitrile gloves. The sterile surgical gowns followed the same pattern with a median invoice price of $3.39 as compared to the CY 2021 price of $5.02. We do not believe that the typical price for these supplies has undergone significant decreases as a result of the PHE and we are not finalizing any price changes at this time pending additional discussion with stakeholders. For the patient gown (SB026) supply, the median price of the 43 submitted invoices was $0.51 and the average price was $0.67. We believe that this additional data supports the current CY 2021 price of $0.58 and we are not finalizing a price change since the invoice data suggested that the current price remains typical during the PHE. We also received a small quantity of invoices associated with other PPE supplies but we did not believe that we had enough data in these cases to determine typical pricing and therefore we are not finalizing any additional price changes to supply items.

As described in section VIII. of this final rule, Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million. We do not have authority to waive the budget neutrality provision for CPT code 99072 unless explicitly stated by statute. In addition, as described in section II.B. of this rule (PE section), we also disagree with the stakeholders that utilization assumptions for equipment should be revisited as part of the public health emergency. While we agree that many services had a reduced volume of Medicare beneficiaries at times during CY 2020, we note that equipment costs under the PFS are amortized across the full useful life of the equipment, which in the vast majority of cases is 5–10 years. We believe that it would distort relativity to apply a temporary decrease in utilization caused by the PHE to the pricing structure of the equipment's full useful life duration. We also note that we do not have statutory authority to exempt any modifications to the equipment utilization assumptions from budget neutrality calculations.

c. Waiver of Proposed Rulemaking Provisions

Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b), an agency is generally required to publish a notice and solicit comment on a proposed rule in the **Federal Register** before issuing a final rule. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. The APA provides for exceptions from the notice and comment requirements, *see* 5 U.S.C. 553(b)(B); in cases in which the APA exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of Title 5 and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements if the agency for good cause finds that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to the September 2020 creation of CPT code 99072 which did not allow for its inclusion in the proposed rule. We believe that establishing payment for this service on an interim basis will allow for its provision as a bundled service during the public health emergency. We find that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing these

payment policies on an interim basis. We also find that delaying implementation of these policies is unnecessary because the impact on other PFS services for 2021 is negligible and the practical alternative for this treatment is no payment under Medicare Part B. In either case, payments for 2022 and beyond would be informed by public comments.

Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 1871(b)(2)(C) of the Act and section 533(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document. We are seeking interim final comment on our general approach to CPT code 99072, as well as how to think about services that may not include these specific PPE items but for which there are incurred costs as described by the stakeholders. Additionally, we will consider the market cost for these supply items relative to the changing conditions in the market, as appropriate.

(51) Chronic Care Management Services (CPT Code 99439 and HCPCS Code G2058)

We established payment for HCPCS code G2058 (*Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month*) in the CY 2020 PFS final rule (84 FR 62690). At the January 2020 RUC meeting, specialty societies requested a temporary crosswalk through CY 2021 between the value established by CMS for HCPCS code G2058 and the value of new CPT code 99439 (with a descriptor identical to G2058). The Chronic Care Management code family will be resurveyed during CY 2020 and is expected to be presented for review as part of the 2022 RUC review process.

For CY 2021, we proposed the RUC-recommended work RVU of 0.54 and the RUC-recommended direct PE inputs for CPT code 99439.

We received several public comments all in support of our proposed valuations for Chronic Care Management Services (CPT code 99439 and G2058). After consideration of the comments, we are finalizing as proposed.

(52) External Counterpulsation (HCPCS Code G0166)

In the CY 2020 PFS proposed rule (84 FR 40516), an external stakeholder nominated HCPCS code G0166 as potentially misvalued due to concerns that the PE RVUs for this code did not fully reflect the total resources required to deliver the service and CMS proposed G0166 as potentially misvalued. The RUC reviewed the direct PE inputs for HCPCS code G0166 at the October 2019 RUC meeting.

We proposed the RUC-recommended preservice period, service period and postservice period with refinements. We proposed to replace CA010 (*obtain vital signs*) during the postservice of service period with CA023 (*monitor patient following procedure/service, no multitasking*).

For the equipment items, we proposed to update the price of the ''EECP, external counterpulsation system'' (EQ012) equipment to $101,247.50 based on an average of the five invoices submitted along with the recommendations. We noted that the EQ012 equipment is the only current equipment item in our direct PE database with an equipment utilization rate of 25 percent and the only equipment item with a utilization rate under 50 percent. Although we did not propose to change the equipment utilization rate, we solicited feedback from commenters regarding the utilization rate for the EQ012 equipment to help us understand why it should differ from all other medical equipment.

We also received invoices for a series of additional equipment items: An EECP service contract, an EECP compression equipment package, and an EECP electrical equipment package. We did not propose to establish a price for the EECP service contract, as service contracts are considered to be an administrative expense and a form of indirect PE under our methodology. As for the two equipment packages, there were a number of unusual factors involving these items that created difficulties for our equipment methodology. Both equipment packages had a suggested utilization rate of 25 percent, half of our typical utilization rate of 50 percent, and both had a suggested useful life duration of only 3 months. As we stated in section II.B. of the proposed rule (85 FR 50082–50083), Determination of Practice Expense RVUs, we have concerns that assigning very low useful life durations to this type of equipment would fail to maintain relativity with other equipment on the PFS. We also noted that the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. Our current equipment formula is not designed to address cases in which equipment is replaced multiple times per year, and we noted that we believe that applying a multi-year depreciation in these situations would not be reflective of market pricing. Although we agreed that these costs should be reflected in the pricing of HCPCS code G0166, we believed that the very frequent replacement of the items in the two equipment packages makes them a poor fit under our equipment methodology.

Therefore, we proposed to treat the two EECP equipment packages as supplies instead of treating them as equipment. We proposed to establish the EECP compression equipment package (SD341) as a supply with a cost of $645 based on an average of the submitted invoices, and proposed to establish the EECP electrical equipment package (SD342) as a supply with a cost of $500 again based on an average of the submitted invoices. Based on information provided by stakeholders, we proposed a supply quantity of 1/325 for these two items (0.00308) based on the supply being used on average five times per day and replaced every 3 months (5 uses * 5 days * 13 weeks = 325). We noted that we believe that assigning these two items as supplies rather than equipment more accurately captures the unusual circumstances associated with providing this service.

We received public comments on External Counterpulsation. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with CMS's proposal to move 3 minutes of clinical labor time for checking vitals at the end of the session to post-procedure monitoring, stating this is not monitoring in the sense of the CA023 activity code but taking vitals to evaluate the effectiveness of the treatment and the patient's condition.

Response: We disagree with the commenters and continue to believe our proposal to replace CA010 (*obtain vital signs*) during the postservice of the service period with CA023 (*monitor patient following procedure/service, no multitasking*) was appropriate. We understand that the clinical labor taking place is not a monitoring activity, however the CA010 activity code is used to describe clinical labor that takes place before the service occurs, not afterward. We proposed to use the CA023 activity code as the closest proxy available to describe this clinical labor. We note that there is no change in valuation for the service as we proposed the same 3 minutes for the CA023 activity code as the RUC recommended under the CA010 activity code.

Comment: Several commenters disagreed with the proposal to price the

''EECP, external counterpulsation system'' (EQ012) equipment at $101,247.50. Commenters stated that one of the previous invoices used for pricing the EQ012 equipment reflected a discount of $10,000 and was not for the purchase of a new ECP system. Commenters stated that although it was not explicitly listed, it was highly likely that another invoice used for pricing was either the result of a trade-in credit or reflected a refurbished system. Commenters submitted a new invoice for the EQ012 equipment with a listed price of $130,890 and requested that CMS use this invoice for pricing while disregarding the prior invoices.

Response: We disagree with the commenters that the previous invoices used for pricing the EQ012 equipment should be disregarded for pricing. We do not agree that invoices from 2015 and 2017 have no validity; while we prefer to use current invoices wherever possible, we also believe in the importance of using multiple data points as opposed to relying on a single invoice. We also note that the same commenter submitted invoices for pricing the supply packages, which ranged in date from 2012 to 2020. We have no indication that the previous invoices were part of trade-in programs, and our pricing methodology uses the actual market rate for supplies/equipment, which does include discounts. We also do not agree with the commenter that the use of new equipment would be typical in all cases as it is clear that providers of these services can and do purchase used versions of the EQ012 equipment. As a result, we are employing our standard policy for invoice submissions and averaging together the previously submitted invoices with the new invoice submission, which results in a price of $111,128.30 for the EQ012 equipment. We are finalizing this as the new price for the EECP, external counterpulsation system.

Comment: Several commenters supported the current equipment utilization rate of 25 percent for the EQ012 equipment. Commenters stated that this rate reflected 80 minutes (proposed nonfacility time) × 1.57 services per day × 5 days per week × 50 weeks = 31,400 minutes for a total utilization rate of 20.9 percent (31,400 divided by 150,000). Commenters stated that the utilization rate was accurate based on their experience delivering this service and their discussions with other ECP therapy providers in different regions across the country. One commenter disagreed with the proposed equipment utilization rate of 25 percent and requested that CMS review the equipment utilization for this service and explain why it differs from all other medical equipment.

Response: We appreciate the additional information provided by the commenters regarding the utilization rate for the EQ012 equipment. Based on the information supplied by the commenters, we continue to believe that the current equipment utilization rate of 25 percent is the most accurate value for this unique type of equipment.

Comment: Several commenters provided feedback on the proposal to establish the EECP compression equipment package (SD341) and the EECP electrical equipment package (SD342) as disposable supplies. Commenters were supportive of the concept of treating these items as supplies instead of as equipment and provided additional details regarding the supply contents and supply quantities. Commenters stated that the EECP compression equipment package (SD341) supply should contain eight total inputs consisting of cuffs, bladders, hoses, straps, connectors, and specialized treatment pants. Several commenters stated that the total cost for the SD341 supply package summed to $847.00 while other commenters stated the cost of the same supply to be $826.75. For the EECP electrical equipment package (SD342), commenters stated that CMS accurately captured the finger plethysmograph and ECG cable in this package while omitting the Spo2 probe. Commenters stated that the Spo2 probe is a required item needed to perform the pulse oximetry and the price of the SD342 package should be updated to $752.00. Commenters submitted an extensive list of invoices to support these requested prices.

Response: We appreciate the additional information provided by the commenters regarding these supply packages, especially the pricing data contained in the submitted invoices. For the SD341 compression equipment package, we note that the invoices show that the two sets of cuffs are often sold together at a price of $220 instead of separately at $245. This accounts for the difference between the $847.00 and $826.75 prices listed by different commenters, and since the bundling of these cuffs appears to be the typical case, we are finalizing an update in the price of the EECP compression equipment package (SD341) supply at $826.75. For the second supply package, we agree with the commenters and we are finalizing an update in the price of the EECP electrical equipment package (SD342) at $752.00.

Comment: Several commenters provided additional details regarding the quantities for the two supply packages. Commenters stated that the compression package items typically have to be replaced every 13 weeks while the electrical package items typically have to be replaced every 50 weeks. Commenters stated that a provider of these services would be highly unlikely to be able to use the same cuffs, bladders, hoses, and straps in the SD341 supply package for 325 hours as these items would be completely deteriorated by this point and would be likely to lose the structural integrity needed to maintain clinical effectiveness. Commenters stated that a 100 hour life span would be more accurate for the SD341 supply as it reflected the typical wear and tear with inflating the compression items at high pressure (300 mm Hg every heartbeat) and was consistent with the manufacturer's estimated usage. Commenters stated that the electrical package does not experience the same level of stress and wear, and instead those items have a 400 hour life span.

Response: We appreciate the additional information provided by the commenters regarding the quantities for these two supply packages. Given that the intraservice treatment time for HCPCS code G0166 lasts for one hour, we are finalizing an update in the quantity of the SD341 supply pack to 1/100 and an update in the quantity of the SD342 supply pack to 1/400. These updated supply quantities reflect how many times the service can be performed before the supply package needs to be replaced.

Comment: Several commenters disagreed with the proposal of the RUC-recommended clinical labor time of 83 minutes. Commenters stated that the proposed time omitted 8 minutes of required clinical activities consistent with the ECP user manual. Commenters stated that ECP therapy providers must check legs, conduct a patient assessment, auscultate/assess lungs, and review change in baseline. Commenters stated that ECP therapy providers also must perform patient checks immediately following the service such as assess signs related to blood sugar levels (for diabetic patients), assess the patient's lower body for redness, blistering, and/or ulceration, and assist patients from the treatment area following the service. Commenters stated that these are essential safety measures to ensure patients have tolerated the treatment well and these activities must be performed every treatment and must be captured as part of the clinical labor time. Commenters

requested that CMS add 8 minutes to the total time under the CA016 activity code (''Prepare, set-up and start IV, initial positioning and monitoring of patient''), increasing the time for this clinical activity from 6 minutes to 14 minutes.

Response: Although we appreciate the additional information supplied by the commenters, we continue to agree with the RUC's recommendation of 83 minutes of total clinical labor time. The RUC reviewed the same information provided by the commenters and concluded that this additional clinical labor time would not be typical. We also note that the recommended 83 minutes of total clinical labor time already represents an increase over the prior total time of 73 minutes for the service, with additional clinical labor time for preparing and positioning the patient as well as completing post-procedure forms. We believe that the typical clinical labor activities for HCPCS code G0166 are captured in the RUC-recommended clinical labor time.

After considering the comments, we are finalizing the RUC-recommended preservice period, service period, and postservice period clinical labor times for HCPCS code G0166 along with our proposal to replace the CA010 clinical labor time with an equivalent 3 minutes of CA023 clinical labor time. We are also finalizing updates in the price of the EQ012 equipment and the SD341 and SD342 supply packages, along with updates to the supply quantity for the two supply packages.

(53) Molecular Pathology Interpretation (HCPCS Code G0452)

At the October 2018 RUC meeting, the Relativity Assessment Workgroup (RAW) identified HCPCS code G0452 (*Molecular pathology procedure; physician interpretation and report*) as potentially misvalued on a CMS/Other screen. The RUC had never reviewed HCPCS code G0452 and assumptions regarding work and time were based upon a 1995 vignette. In addition, the specialty society noted that the technology available for furnishing the service, as well as the patient population receiving the service, had changed since the code was valued by CMS.

The RUC requested a physician work survey be completed for the October 2019 RUC meeting. It was during the October meeting that the work and PE values for HCPCS code G0452 were reviewed and recommended.

For CY 2021, we proposed the RUC-recommended work RVU of 0.93 and the RUC-recommended direct PE inputs for HCPCS code G0452.

We received several public comments on Molecular Pathology Interpretation (HCPCS code G0452) all in support of our proposal to adopt the RUC's recommendations for the service.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs as proposed.

(54) Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS Codes G2082 and G2083)

In the CY 2020 PFS final rule (84 FR 63102 through 63104), we issued an interim final rule with comment period (IFC) to establish coding and payment for E/M, observation, and the provision of self-administered Esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible. We created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis. For CY 2020, we established RVUs for these services that reflect the relative resource costs associated with the E/M, observation and provision of the self-administered esketamine product. The HCPCS G-codes are described as follows: HCPCS code G2082 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation*) and HCPCS code G2083 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation*).

In developing the interim final values for these codes, we used a building block methodology that sums the values associated with several codes. For the overall E/M and observation elements of the services, we incorporated the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*), which has a work RVU of 0.48 and a total work time of 16 minutes, which is based on a pre-service evaluation time of 2 minutes, an intraservice time of 10 minutes, and a postservice time of 4 minutes.

We also incorporated CPT codes 99415 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient Evaluation and Management service)*) and 99416 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes (List separately in addition to code for prolonged service)*)) in which neither code has a work RVU, but includes direct PE inputs reflecting the prolonged time for clinical staff under the direct supervision of the billing practitioner.

In addition, to account for the cost of the provision of the self-administered esketamine as a direct PE input, we incorporated the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, we used a price of $590.02 for the supply input that describes 56 mg (supply code SH109) and for HCPCS code G2083, we used a price of $885.02 for the supply input describing 84 mg of esketamine (supply code SH110).

We sought comment on the interim final values we established for HCPCS codes G2082 and G2083, including the assigned work RVUs, work times, and direct PE inputs. See the CY 2021 PFS proposed rule (85 FR 50169 through 50172) for a summary of the comments we received and our responses.

After considering the comments we received, we proposed to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that sums the values associated with several codes. For the overall E/M and observation elements of the services, we incorporated the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212. We also proposed to include the clinical labor for CPT codes 95076 and 95079 (in lieu of CPT codes 99415 and 99416 as detailed earlier); and to account for the

cost of the provision of the self-administered esketamine as a direct PE input, we proposed to incorporate the wholesale acquisition cost (WAC) data from the most recent available quarter. We solicited comment on this updated payment proposal and valuation of HCPCS code G2082 and G2083.

We received public comments on the Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS Codes G2082 and G2083). The following is a summary of the comments we received and our responses.

Comment: Overall, commenters were in support of our proposal to refine the values for HCPCS codes G2082 and G2083.

Response: We appreciate the support for our proposal to refine the direct PE inputs of HCPCS codes G2082 and G2083, in part, by using the clinical labor time for CPT codes 95076 and 95079, in lieu of the clinical labor time of CPT codes 99415 and 99416, which increased the clinical labor time from 30 minutes to 150 minutes.

Comment: A commenter stated that administering esketamine may on occasion necessitate a higher level of E/M from the physician, and therefore, encouraged CMS to provide the ability to bill a separate E/M service on those occasions where medical necessity dictates a higher level of service. The commenter also requested that CMS issue a J-code specifically for esketamine treatment and create a HCPCS code that separates the clinical work of the service from the cost of the medication.

Response: HCPCS codes G2082 and G2083 are bundled services that include, as discussed in the CY 2021 PFS proposed rule (85 FR 50169 through 50172), the E/M, observation and the provision of self-administered esketamine. We continue to believe that HCPCS codes G2082 and G2083 should be a bundled services. We do not believe it would be appropriate to create a J-code that could permit esketamine to be billed separately, particularly given that the product is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient.[24] Additionally, we continue to believe that the building block methodology we used incorporating CPT code 99212 is appropriate for valuing this service. Since HCPCS codes G2082 and G2083 already take into account E/M provided as part of these services, it would be duplicative for a clinician to bill for a separate E/M code along with HCPCS codes G2082 and G2083. We believe the direct PE input refinements made for HCPCS codes G2082 and G2083, which increased the clinical labor time to 150 minutes, are appropriate for the necessary observation associated with esketamine administration. However, other reasonable and necessary E/M services may be furnished and billed for a patient on dates before and after HCPCS codes G2082 and G2083, for example, when the services are furnished in the course of treating and diagnosing treatment-resistant depression. Additionally, the self-administered esketamine is considered a supply item for this bundled service. Therefore, esketamine cannot be billed separately along with HCPCS codes G2082 and G2033 under the PFS.

After consideration of public comments, we are finalizing our proposal to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that sums the values associated with several codes.

(55) Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

In the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD). The codes and descriptors we finalized for CY 2020 were:

- HCPCS code G2086: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code G2087: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

As noted in the CY 2020 PFS final rule (84 FR 62673), if a patient's treatment involves MAT, this bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged.

As discussed in the CY 2021 PFS proposed rule (85 FR 50172), we received requests to expand these bundled payments to be inclusive of other SUDs, not just OUD. We agreed that doing so could expand access to needed care. We proposed to expand these bundled payments to be inclusive of all SUDs. To accomplish this, we proposed to revise the code descriptors for HCPCS codes G2086, G2087, and G2088 by replacing ''opioid use disorder'' with ''a substance use disorder.'' The payment and billing rules would otherwise remain unchanged. We noted that HCPCS codes G2086, G2087, and G2088 were added to the Medicare Telehealth list in the CY 2020 PFS final rule (84 FR 62628). The revised code descriptors are:

- HCPCS code G2086: *Office-based treatment for a substance use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code G2087: *Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

In addition, in the CY 2020 PFS final rule we stated that we anticipated that the services described by HCPCS codes G2086, G2087, and G2088 would often be billed by addiction specialty practitioners, but note that these codes are not limited to any particular physician or NPP specialty. We also noted that consultation was not a required condition of payment for these codes, but that consultation with a specialist could be counted toward the minutes required for billing HCPCS codes G2086, G2087, and G2088 (84 FR 62674). Although it is not a requirement for billing the code, we encouraged that practitioners consult with specialists in cases where it is warranted and refer the patient to specialty care as needed.

[24] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

We noted that while these codes describe treatment for any SUD, information about which specific SUDs are being treated would provide valuable information that can help assess local, state, and national trends and needs. We believe it is important that the diagnosis codes listed on the claim form reflect all SUDs being treated; however, we also noted that we do not wish to add any additional burden on practitioners related to claims submission, and therefore, we solicited information on whether there are sources of data we could explore in order to provide this information. We also solicited information on whether there are differences in the resource costs associated with furnishing services for the various SUDs, and accordingly whether there is a need for more stratified coding to describe these services. We noted that in some instances, the CPT Editorial Panel has created CPT codes to replace G codes created by CMS, and that we welcomed such input on those services.

We received public comments on the proposal to expand these bundled payments to be inclusive of all SUDs. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported this proposal. Some noted that this flexibility would permit practitioners to furnish comprehensive services for individuals with SUDs, the majority of whom have polysubstance use disorder. One commenter noted that every service code can have one or more diagnosis codes connected to it on a claim, therefore, a generic SUD treatment code still permits physicians to specify which SUDs were treated, allowing CMS to track that information without adding additional administration burden. Some commenters also stated they were not aware of any significant variation in resource costs between SUDs. One stakeholder encouraged CMS to work with the medical societies through the CPT Editorial Panel process to examine the different resource costs involved in treating different SUDs to determine the need for more stratified coding, but advised that in the meantime, CMS should finalize the proposal to ensure that more patients have access to these critical services. A few commenters suggested that these codes should account for risk stratification, noting that some patients, such as pregnant or postpartum women have more complex needs and require more frequent services. One commenter stated that expanding the use of these codes to all SUD diagnoses may present opportunity for fraudulent, duplicative coding, were providers to bill the codes for each SUD diagnosis, noting that many patients with SUD use multiple substances and require treatment for more than one substance, therefore, the commenter recommended that CMS limit billing of these codes to once per month per patient.

Response: We thank the commenters for their feedback. After consideration of the comments, we are finalizing our proposal to expand the bundled payments described by HCPCS codes G2086–G2088 to be inclusive of all SUDs. We appreciate the commenter that pointed out that duplicative billing could occur in cases where a beneficiary is being treated for more than one SUD. We agree that HCPCS codes G2086–G2088 should not be billed more than once per month per beneficiary since these codes describe treatment for one or more SUDs. Additionally, we welcome the opportunity to work with the medical societies and CPT Editorial Panel to determine whether there is a need to stratify this coding to reflect variation in service intensity, through future rulemaking.

(56) Initiation of Medication Assisted Treatment (MAT) in the Emergency Department (HCPCS Code G2213)

In the CY 2020 PFS proposed rule (84 FR 40545), we sought comment on the use of medication assisted treatment (MAT) in the emergency department (ED) setting, including initiation of MAT and the potential for either referral or follow-up care, to better understand typical practice patterns to help inform whether we should consider making separate payment for such services in future rulemaking. We noted that the term MAT generally refers to treatment of OUD that includes both an FDA-approved medication for the treatment of OUD and behavioral/psychosocial treatment, but that care provided in the ED typically would include medication for the treatment of OUD and referral or linkage to primary care or a hospital-based bridge clinic for continuation of medication and potentially other services, including counseling and other psychosocial services.

The public comments received in response to the comment solicitation were supportive of us making a proposal, several citing research that indicates improved outcomes for patients who initiate medications for the treatment of OUD in the ED. One commenter noted that by implementing this treatment regimen, practitioners can address a patient's immediate withdrawal symptoms, which allows time to coordinate care and provide a referral to substance use disorder specialists and other community resources who can appropriately carry out long-term treatment. Another commenter cited that the national rate of overdose-related visits seen in EDs nearly doubled between 2005 and 2014 and noted that hospital-based care represents a critical opportunity to initiate treatment and connect patients with OUD to care, noting that patients who receive information about drug treatment in the hospital post-overdose are more likely to seek treatment.[25] The commenter also cited a randomized clinical trial that showed that more patients were engaged in treatment 30 days after buprenorphine was initiated in the ED and coupled with a referral, compared to interventions that did not include buprenorphine.[26] Another study found that ED induction of buprenorphine was more cost-effective than either brief intervention or referral upon discharge.[27] One commenter suggested that CMS institute a G-code to address this coding gap in the short term, while a more permanent solution is pursued to address this site-of-service specification.

We were persuaded by the comments received in response to our comment solicitation that this work is not currently accounted for in the existing code set. To account for the resource costs involved with initiation of medication for the treatment of opioid use disorder in the ED and referral for follow-up care, we proposed to create one add-on G-code to be billed with E/M visit codes used in the ED setting. We discussed that this code would include payment for assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services, but we note that the drug itself would be paid separately. We proposed the following code:

- HCPCS code GMAT1: *Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive*

[25] Agency for Healthcare Research and Quality, ''Statistical Brief #219: Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009–2014,'' (2017), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.*

[26] Gail D'Onofrio et al., ''Emergency Department—Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence Randomized Clinical Trial,'' *JAMA* 16, no. 313 (2015): 2002–2010, *https://www.ncbi.nlm.nih.gov/pubmed/25919527.*

[27] Susan Busch et al., ''Cost Effectiveness of Emergency Department—Initiated Treatment for Opioid Dependence,'' *Journal of Addiction* 11, no. 112 (2017), *https://www.ncbi.nlm.nih.gov/pubmed/28815789.*

services (List separately in addition to code for primary procedure).

To price this service, we proposed to use a direct crosswalk to the work and direct PE inputs for HCPCS code G0397 (*Alcohol/subs interv >30 min*), which is assigned a work RVU of 1.30. We noted that we believe that the work and PE described by this crosswalk code is similar in nature and magnitude to the services described in HCPCS code GMAT1. We noted that unlike the requirements for reference code, we did not propose a required number of minutes to bill HCPCS code GMAT1. We welcomed comment on the proposal and whether we should consider a different valuation to account for the resource costs involved with these services.

We received public comments on our proposal to create an add-on G-code to be billed with E/M visit codes used in the ED setting. The following is a summary of the comments we received and our responses.

Comment: Commenters were very supportive of finalizing this proposal, noting that payment for this service will encourage hospitals to engage in this evidence-based practice. One commenter sought clarification on which of these elements were mandatory given that ''initiation'' of the service for patients will involve a transition of care to other health care providers and requested that CMS provide guidance on what ''follow-up'' is required of the emergency department provider given that post-initiation care is administered by the practitioner to whom the ED provider would have transitioned the patient care.

Response: We are finalizing payment for this code as proposed. We note that HCPCS code GMAT1 was a placeholder code in the proposed rule. The finalized code is HCPCS code G2213 (*Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (List separately in addition to code for primary procedure)*). In response to the request for clarification about which elements are required in order to bill for this code, practitioners should furnish only those activities that are clinically appropriate for the beneficiary that is being treated.

(57) Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS Codes G2170 and G2171)

We received a comment in response to the CY 2020 PFS proposed rule (84 FR 40481), as well as inquiries from stakeholders, requesting that we establish new coding for the percutaneous creation of an arteriovenous fistula (AVF) used for dialysis access.

For CY 2019, based on two new technology applications for arteriovenous fistula creation, we established two new HCPCS codes to describe the two modalities of this service. Specifically, we established HCPCS code C9754 (*Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)*) and HCPCS code C9755 (*Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed*). The HCPCS codes were created for institutional payment systems, and thus do not allow for payment for the physician's work portion of the service. Stakeholders have stated that the lack of proper coding to report the physician work associated with these procedures is problematic, as physicians are either billing an unlisted procedure code, or are billing other CPT codes that do not appropriately reflect the resource cost associated with the physician work portion of the service. Stakeholders stated that separate coding for physician payment will allow billing when the procedures are furnished in either a physician office or an institutional setting, and be paid under the respective payment systems, as appropriate. We have recognized that the lack of appropriate coding for this critical physician's service has become an even greater burden given the PHE for COVID–19. In order to mitigate potential health risks to beneficiaries, physicians and practitioners as a result of having this procedure performed in an institutional setting, we created two HCPCS G codes for percutaneous creation of an arteriovenous fistula (AVF). The codes are contractor priced and effective July 1, 2020. This will allow for more accurate billing and coding of a crucial physician service that could then be performed in both institutional and office settings, thus mitigating unnecessary risk to beneficiaries, physicians and practitioners caused by disease transmission. The HCPCS G codes are described as follows:

- HCPCS G code G2170 (*Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed.*)
- HCPCS G code G2171 (*Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed.*)

We proposed to maintain contractor pricing for these HCPCS codes for CY 2021, however, we also solicited information from stakeholders on the resource costs involved in furnishing the services described by HCPCS codes G2170 and G2171 to ensure proper payment for these physician's services, for consideration in future rulemaking. We noted that under the OPPS these services are assigned to APC 5193, which for CY 2020 has an assigned payment rate of $15,938.20.

We received public comments on Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS code G2170 and G2171).

The following is a summary of the comments we received and our responses.

Comment: Commenters stated that they were supportive of the creation of the HCPCS codes G2170 and G2171. Many commenters stated that they believe this will increase access for beneficiaries by allowing this service to be performed in outpatient settings. Commenters were also appreciative of the creation of these codes for use during the PHE.

Response: We appreciate the commenters' support of the creation of HCPCS codes G2170 and G2171.

Comment: A few commenters stated that they did not understand the logic of our proposal to contractor price HCPCS codes G2170 and G2171 to avoid disease transmission.

Response: We believe that our statement about reduced risk of disease transmission in connection with our proposal to maintain contractor pricing

for calendar year 2021 for HCPCS codes G2170 and G2171 may have been confusing to some commenters. We created HCPCS codes G2170 and G2171 to facilitate provision of these services outside of institutional facility settings. We stated that expanded access to this service outside of facility settings, especially in light of the PHE for COVID–19, could reduce the potential health risks to beneficiaries, physicians and other health care practitioners that could occur when these services are furnished in higher acuity health care settings. The proposal to contractor price these services was not related to risks of disease transmission.

Comment: Commenters stated that they believe HCPCS codes G2170 and G2171 should be nationally priced for calendar year 2021 and beyond. The commenters stated that they believe contractor pricing creates unnecessary variability and unreliable payment.

Response: CMS routinely contractor prices new HCPCS codes. The services described by G2170 and G2171 are new technology and are just beginning to be performed outside of the facility setting. As such, we anticipate collecting more information for purposes of national pricing. We expect to take these comments into consideration for future rulemaking and we hope to continue a dialogue with stakeholders on these important services.

Comment: A few commenters stated that they are displeased with the publication of a proposed Local Coverage Determination (LCD) that would limit coverage for these services.

Response: We appreciate the concern of some commenters regarding a proposed LCD for HCPCS codes G2170 and G2171. We did not address coverage policies for these services in the proposed rule. Such local coverage policies are not within the scope of the CY 2021 PFS rulemaking process.

Comment: A few commenters responded to our request for information from stakeholders on the resource costs involved in furnishing the services described by HCPCS codes G2170 and G2171 for consideration in future rulemaking. Some commenters submitted invoices for various equipment as well as a breakdown of their estimated supply and clinical staff costs.

Response: We appreciate the information commenters provided on the resource costs involved in furnishing these services. We will take this information into consideration for future rulemaking.

After consideration of these public comments, we are finalizing our proposals for HCPCS codes G2170 and G2171 with contractor pricing as proposed, and will consider addressing national pricing through potential future rulemaking.

(58) Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System (Category III CPT Codes 0446T, 0447T, and 0448T)

Category III CPT codes 0446T, 0447T, and 0448T describe the services related to the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor from subcutaneous pocket, in a subcutaneous pocket via incision. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provides glucose trend information, and signal alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The codes that describe the implantation, removal, and removal and implantation of implantable interstitial glucose sensors are currently contractor-priced.

- Category III CPT code 0446T (*Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training*);
- Category III CPT code 0447T (*Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision*); and
- Category III CPT code 0448T (*Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation*).

In the CY 2020 PFS final rule (84 FR 62627), we requested information from stakeholders to ensure proper payment for this important physician's service and welcomed recommendations on appropriate valuation for these services to be considered in future rulemaking.

We proposed to establish national payment amounts for the codes describing the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor, effective January 1, 2021. We proposed a work RVU of 1.14 for Category III CPT code 0446T, a work RVU of 1.34 for Category III CPT code 0447T, and work RVU of 1.91 for Category III CPT code 0448T based on a crosswalk to the work RVUs, work time, and direct PE inputs of CPT codes 11981 (*Insertion, non-biodegradable drug delivery implant*), 11982 (*Removal, non-biodegradable drug delivery implant*), and 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant*), respectively, due to the similar clinical nature of these procedures.

We also proposed to include one supply and one equipment item to the direct PE inputs crosswalked from CPT codes 11981–11983. We added a new ''implantable interstitial glucose sensor'' (supply code SD334) for Category III CPT codes 0446T and 0448T to include the supply costs of the ''implantable interstitial glucose sensor'' (supply code SD334) included in these procedures, which we proposed to price at $1,500.00, based on information we received from stakeholders. We also proposed to include the smart transmitter associated with the use of this implantable interstitial glucose sensor. We proposed to price the smart transmitter involved in furnishing this service by using a similar equipment item finalized in the CY 2019 PFS final rule (83 FR 59624) as a proxy, the ''heart failure patient physiologic monitoring equipment package'' (EQ392); the EQ392 has a price of $1,000.00, and is similarly used for long term remote monitoring of patients. We proposed to use the EQ392 equipment as a proxy for the valuation of the smart transmitter associated with the implantable interstitial glucose sensor, to which we are assigning a time of 25,920 minutes for EQ392 in Category III CPT codes 0446T and 0448T. We explained that this time is derived from 60 minutes per hour times 24 hours per day times 90 days per billing quarter, divided by 1 minute of equipment use out of every 5 minutes of time. We did not include the implantable interstitial glucose sensor or the EQ392 equipment proxy for Category III CPT code 0447T, as it describes only a removal procedure.

We solicited comment on the proposed values for these Category III CPT codes (0446T, 0447T, and 0448T), and we solicited comment on the appropriateness and accuracy of the proposed work RVUs, work times, and direct PE inputs.

We received public comments on the Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System code family. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposed work RVUs for the Category III CPT codes, 1.14 for Category III CPT code 0446T, 1.34 for Category III CPT code 0447T, and 1.91 for Category III CPT code 0448T.

Response: We appreciate the support for the proposed work RVUs for these Category III CPT codes (0446T, 0447T, and 0448T).

Comment: Several commenters stated that they agreed with the inclusion of

the ''implantable interstitial glucose sensor'' supply (SD334) for Category III CPT codes 0446T and 0448T, which should include the supply costs of the implantable interstitial glucose sensor at the proposed price of $1,500.00. However, the commenters stated that the cost of the smart transmitter equipment (EQ392) associated with the use of the implantable interstitial glucose sensor should be included only for Category III CPT code 0446T and not be included as part of the cost of Category III CPT code 0448T. A commenter stated that the 90-day implantable sensor will be implanted for the first time and linked to the transmitter device in the first procedure, Category III CPT code 0446T. The commenter stated that there is no need to report the cost of the transmitter with Category III CPT 0448T as the sensor will be removed and replaced, but the patient will not receive a new smart transmitter during this visit.

Response: We appreciate the additional information supplied by the commenter regarding the use of the smart transmitter equipment in Category III CPT codes 0446T and 0448T. Given that there is no need to report the cost of the transmitter with Category III CPT 0448T because the sensor will be removed and replaced, but the patient will not receive a new smart transmitter during this visit, we are finalizing the removal of the heart failure patient physiologic monitoring equipment package (EQ392) from Category III CPT code 0448T.

After consideration of public comments, we are finalizing the work RVUs as proposed for Category III CPT codes 0446T, 0447T, and 0448T, and finalizing the direct PE inputs as proposed except that we are removing the equipment package (EQ392) from the Category III CPT code 0448T in response to comments as explained above.

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TABLE 28: CY 2021 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	0.00	1.14	1.14	Yes
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	0.00	1.34	1.34	Yes
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	0.00	1.91	1.91	Yes
10004	Fine needle aspiration biopsy, without imaging guidance; each additional	0.80	0.80	0.80	No
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	1.46	1.46	1.46	No
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion	1.00	1.00	1.00	No
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	1.81	1.81	1.81	No
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	1.18	1.18	1.18	No
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	2.26	2.26	2.26	No
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion	1.65	1.65	1.65	No
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	C	C	C	No
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion	C	C	C	No
10021	Fine needle aspiration biopsy, without imaging guidance; first lesion	1.03	1.03	1.03	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion	11.49	11.49	11.49	No
11970	Replacement of tissue expander with permanent implant	8.01	7.49	7.49	No
11971	Removal of tissue expander without insertion of implant	3.41	6.50	7.02	No
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	18.23	17.99	17.99	No
19316	Mastopexy	11.09	11.09	11.09	No
19318	Breast reduction	16.03	16.03	16.03	No
19325	Breast augmentation with implant	8.64	8.12	8.12	No
19328	Removal of intact breast implant	6.48	6.92	7.44	No
19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)	8.54	9.00	9.00	No
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)	13.99	10.48	10.48	No
19342	Insertion or replacement of implant on separate day from mastectomy	12.63	10.48	10.48	No
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)	18.50	14.84	14.84	No
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy	9.17	9.17	9.17	No
19371	Peri-implant capsulectomy, breast, complete, including removal of all intra-capsular contents	10.62	9.98	9.98	No
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in	10.41	11.17	11.17	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	implant-based reconstruction)				
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	20.72	19.60	19.60	No
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	20.72	19.60	19.60	No
28820	Amputation, toe; metatarsophalangeal joint	5.82	3.51	3.51	No
28825	Amputation, toe; interphalangeal joint	5.37	3.41	3.41	No
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])	7.60	7.03	7.03	No
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])	8.36	7.98	7.98	No
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	NEW	2.80	2.80	No
32408	Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed	NEW	3.18	3.18	No
33741	Transcatheter atrial septostomy (TAS) for	NEW	14.00	14.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (e.g., Rashkind, Sang-Park, balloon, cutting balloon, blade)				
33745	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt	NEW	20.00	20.00	No
33746	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location	NEW	8.00	8.00	No
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only	7.90	6.75	6.75	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture	11.63	8.84	8.84	No
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), separate and distinct session from insertion	3.75	3.55	3.55	No
33993	Repositioning of percutaneous right or left heart ventricular assist device, with imaging guidance, at separate and distinct session from insertion	3.26	3.10	3.10	No
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only	NEW	6.75	6.75	No
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, separate and distinct session from insertion	NEW	3.00	3.00	No
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	2.39	2.39	2.39	No
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	4.57	4.57	4.57	No
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	NEW	17.73	17.73	No
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	7.97	11.63	11.63	No
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	11.66	11.66	11.66	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	17.03	17.03	17.03	No
57465	Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect	NEW	0.81	0.81	No
67028	Intravitreal injection of a pharmacologic agent (separate procedure)	1.44	1.44	1.44	No
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral	NEW	3.00	3.00	No
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral	NEW	4.27	4.27	No
70030	Radiologic examination, eye, for detection of foreign body	0.17	0.18	0.18	No
70450	Computed tomography, head or brain; without contrast material	0.85	0.85	0.85	No
70460	Computed tomography, head or brain; with contrast material	1.13	1.13	1.13	No
70470	Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
71250	Computed tomography, thorax, diagnostic; without contrast material	1.16	1.08	1.08	No
71260	Computed tomography, thorax, diagnostic; with contrast material(s)	1.24	1.16	1.16	No
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections	1.38	1.25	1.25	No
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)	NEW	1.08	1.08	No
74300	Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation	0.36	0.27	0.27	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
74328	Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation	0.70	0.47	0.47	No
74329	Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation	0.70	0.47	0.47	No
74330	Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation	0.90	0.56	0.56	No
75820	Venography, extremity, unilateral, radiological supervision and interpretation	0.70	1.05	1.05	No
75822	Venography, extremity, bilateral, radiological supervision and interpretation	1.06	1.48	1.48	No
75984	Change of percutaneous tube or drainage catheter with contrast monitoring (e.g., genitourinary system, abscess), radiological supervision and interpretation	0.72	0.83	0.83	No
76145	Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report	NEW	0.00	0.00	No
76513	Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy, unilateral or bilateral	0.66	0.53	0.60	No
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day	0.00	0.00	0.00	No
77520	Proton treatment delivery; simple, without compensation	C	C	C	No
77522	Proton treatment delivery; simple, with compensation	C	C	C	No
77523	Proton treatment delivery; intermediate	C	C	C	No
77525	Proton treatment delivery; complex	C	C	C	No
90460	Immunization administration through 18	0.17	0.18	0.17	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered				
90461	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered	0.15	0.09	0.15	No
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	0.17	0.18	0.17	No
90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)	0.15	0.09	0.15	No
90473	Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)	0.17	0.18	0.17	No
90474	Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)	0.15	0.09	0.15	No
91200	Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report	0.27	0.21	0.21	No
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	0.00	0.00	0.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	0.37	0.32	0.32	No
92229	Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral	NEW	0.00	C	No
92517	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP)	NEW	0.80	0.80	No
92518	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; ocular (oVEMP)	NEW	0.80	0.80	No
92519	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP) and ocular (oVEMP)	NEW	1.20	1.20	No
92584	Electrocochleography	0.00	1.00	1.00	No
92650	Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis	NEW	N	N	No
92651	Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report	NEW	1.00	1.00	No
92652	Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report	NEW	1.50	1.50	No
92653	Auditory evoked potentials; neurodiagnostic, with interpretation and report	NEW	1.05	1.05	No
93000	Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report	0.17	0.17	0.17	No
93005	Electrocardiogram, routine ECG with at least 12 leads; tracing only,	0.00	0.00	0.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	without interpretation and report				
93010	Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only	0.17	0.17	0.17	No
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional	0.52	0.39	0.39	No
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)	0.00	0.00	0.00	No
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report	0.00	0.00	0.00	No
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional	0.52	0.39	0.39	No
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	NEW	0.50	C	No
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage;	NEW	0.00	0.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	recording (includes connection and initial recording)				
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	NEW	0.00	C	No
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	NEW	0.50	0.50	No
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	NEW	0.55	C	No
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	NEW	0.00	0.00	No
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	NEW	0.00	C	No
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	NEW	0.55	0.55	No
93306	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with	1.50	1.46	1.46	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	spectral Doppler echocardiography, and with color flow Doppler echocardiography				
93623	Programmed stimulation and pacing after intravenous drug infusion	2.85	0.98	0.98	No
93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation	2.80	1.44	1.44	No
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report	0.92	0.75	0.75	No
94010	Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation	0.17	0.17	0.17	No
94060	Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration	0.27	0.22	0.22	No
94617	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; with electrocardiographic recording(s)	0.70	0.70	0.70	No
94618	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)	0.48	0.48	0.48	No
94619	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without	NEW	0.49	0.49	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	electrocardiographic recording(s)				
94621	Cardiopulmonary exercise testing, including measurements of minute ventilation, CO2 production, O2 uptake, and electrocardiographic recordings	1.42	1.42	1.42	No
94640	Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device	0.00	0.00	0.00	No
94667	Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation	0.00	0.00	0.00	No
94668	Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; subsequent	0.00	0.00	0.00	No
94669	Mechanical chest wall oscillation to facilitate lung function, per session	0.00	0.00	0.00	No
95012	Nitric oxide expired gas determination	0.00	0.00	0.00	No
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.60	0.48	0.60	No
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)	0.50	0.32	0.50	No
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.65	0.48	0.65	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)	0.55	0.32	0.55	No
99072	Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease.	NEW	0.00	B	No
99202	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15-29 minutes of total time is spent on the date of the encounter	0.93	0.93	0.93	Yes
99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30-44 minutes of total time is spent on the date of the encounter	1.42	1.60	1.60	Yes
99204	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45-59 minutes of total time is spent on the date of the encounter	2.43	2.60	2.60	No
99205	Office or other outpatient visit for the evaluation and management of a new	3.17	3.50	3.50	Yes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60-74 minutes of total time is spent on the date of the encounter				
99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal	0.18	0.18	0.18	No
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter	0.48	0.70	0.70	Yes
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter	0.97	1.30	1.30	No
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter	1.50	1.92	1.92	Yes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter	2.11	2.80	2.80	No
99417	Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes	NEW	0.61	I	No
99439	Chronic care management services, with the following required elements: * multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, * chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, * comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	NEW	0.54	0.54	No
G0166	External counterpulsation, per treatment session	0.00	0.00	0.00	No
G0452	Molecular pathology procedure; physician interpretation and report	0.37	0.93	0.93	No
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of	0.48	0.70	0.70	Yes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation				
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	0.48	0.70	0.70	Yes
G2170	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	NEW	0.00	0.00	No
G2171	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	NEW	0.00	0.00	No
G2211	Visit complexity inherent to evaluation and	NEW	0.33	0.33	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)				
G2212	Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services) "(Do not report G2212 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416). (Do not report G2212 for any time unit less than 15 minutes))	NEW	-	0.61	No
G2213	Initiation of medication assisted treatment in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (List separately in addition to code for primary procedure)	NEW	1.30	1.30	No
G2214	Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of	NEW	0.77	0.77	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional				
G2215	Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2216	Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2250	Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.	NEW	0.18	0.18	No
G2251	Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of clinical discussion	NEW	0.25	0.25	No

TABLE 29: CY 2021 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
10005	Fna bx w/us gdn 1st les	EF015	mayo stand	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10005	Fna bx w/us gdn 1st les	EF023	table, exam	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
10005	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, portable	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.30
10007	Fna bx w/fluor gdn 1st les	ED050	Technologist PACS workstation	NF		49	47	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
10007	Fna bx w/fluor gdn 1st les	EF015	mayo stand	NF		44	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10007	Fna bx w/fluor gdn 1st les	EL014	room, radiographic-fluoroscopic	NF		44	34	E2: Refined equipment time to conform to established policies for highly technical equipment	-22.75
10009	Fna bx w/ct gdn 1st les	EF015	mayo stand	NF		52	50	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
10021	Fna bx w/o img gdn 1st les	EF015	mayo stand	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10021	Fna bx w/o img gdn 1st les	EF023	table, exam	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
28820	Amputation of toe	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-3.70
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.48
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.81

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.48
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.81
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.11
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-3.70
28825	Partial amputation of toe	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28825	Partial amputation of toe	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	5	2	L1: Refined time to standard for this clinical labor task	-1.11
67028	Injection eye drug	L038A	COMT/COT/RN/CST	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-0.76
71271	Ct thorax lung cancer scr c-	L037D	RN/LPN/MTA	NF	Coordinate post-procedure services	6	4	G1: See preamble text	-0.74
71271	Ct thorax lung cancer scr c-	L046A	CT Technologist	NF	Provide education/o	3	2	L1: Refined time to standard for this clinical labor task	-0.46

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					btain consent				
76513	Oph us dx ant sgm us uni/bi	L038A	COMT/COT/RN/CST	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	2	G1: See preamble text	-0.38
77401	Radiation treatment delivery	ER119	Lead Room	NF		19	0	G1: See preamble text	-0.87
77401	Radiation treatment delivery	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-0.74
92229	Img rta detc/mntr ds poc aly	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	2	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.37
93241	Ext ecg>48hr<7 d rec scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	36	31	G1: See preamble text	-1.85
93241	Ext ecg>48hr<7 d rec scan a/r	SB022	gloves, non-sterile	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-0.25

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93243	Ext ecg>48hr<7d scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	24	19	G1: See preamble text	-1.85
93245	Ext ecg>7d<15d rec scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	36	31	G1: See preamble text	-1.85
93245	Ext ecg>7d<15d rec scan a/r	SB022	gloves, non-sterile	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-0.25
93247	Ext ecg>7d<15d scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	24	19	G1: See preamble text	-1.85
99202	Office o/p new sf 15-29 min	ED021	computer, desktop, w-monitor	NF		34	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.22
99203	Office o/p new low 30-44 min	ED021	computer, desktop, w-monitor	NF		43	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.28

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
99204	Office o/p new mod 45-59 min	ED021	computer, desktop, w-monitor	NF		54	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.35
99205	Office o/p new hi 60-74 min	ED021	computer, desktop, w-monitor	NF		67	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.43
99211	Office o/p est minimal prob	ED021	computer, desktop, w-monitor	NF		17	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.11
99212	Office o/p est sf 10-19 min	ED021	computer, desktop, w-monitor	NF		28	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.18
99213	Office o/p est low 20-29 min	ED021	computer, desktop, w-monitor	NF		36	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.23
99214	Office o/p est mod 30-39 min	ED021	computer, desktop, w-monitor	NF		51	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
99215	Office o/p est hi 40-54 min	ED021	computer, desktop, w-monitor	NF		62	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.40
99417	Prolng off/op e/m ea 15 min	ED021	computer, desktop, w-monitor	NF		15	0	G6: Indirect Practice Expense input and/or not individually allocable to	-0.10

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								a particular patient for a particular service	
G0166	Extrnl counterpulse, per tx	EQ012	EECP, external counterpulsation system	NF		83	80	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-2.53
G0166	Extrnl counterpulse, per tx	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	0	G1: See preamble text	-1.11
G0166	Extrnl counterpulse, per tx	L037D	RN/LPN/MTA	NF	Monitor patient following procedure/service, no multitasking	0	3	L1: Refined time to standard for this clinical labor task	1.11
G0166	Extrnl counterpulse, per tx	SD341	EECP compression equipment package	NF		0	0.01	G1: See preamble text	8.27
G0166	Extrnl counterpulse, per tx	SD342	EECP electrical equipment package	NF		0	0.003	G1: See preamble text	1.88
G2212	Prolong outpt/office vis	ED021	computer, desktop, w-monitor	NF		15	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.10

TABLE 30: CY 2021 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
28820	Amputation of toe	EF014	light, surgical	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28820	Amputation of toe	EF015	mayo stand	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28820	Amputation of toe	EF031	table, power	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
28820	Amputation of toe	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28820	Amputation of toe	EQ138	instrument pack, medium ($1500 and up)	NF		67	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
28820	Amputation of toe	EQ235	suction machine (Gomco)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28820	Amputation of toe	EQ240	tourniquet system (Zimmer1200)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.18
28825	Partial amputation of toe	EF014	light, surgical	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28825	Partial amputation of toe	EF015	mayo stand	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28825	Partial amputation of toe	EF031	table, power	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
28825	Partial amputation of toe	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		56	50	E15: Refined equipment time to conform to	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								changes in clinical labor time	
28825	Partial amputation of toe	EQ138	instrument pack, medium ($1500 and up)	NF		67	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
28825	Partial amputation of toe	EQ235	suction machine (Gomco)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28825	Partial amputation of toe	EQ240	tourniquet system (Zimmer1200)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.18
67028	Injection eye drug	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		19	17	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
67028	Injection eye drug	EL005	lane, exam (oph)	NF		19	17	E15: Refined equipment time to conform to changes in	-0.25

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								clinical labor time	
71271	Ct thorax lung cancer scr c-	ED050	Technologist PACS workstation	NF		35	34	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
92229	Img rta detc/mntr ds poc aly	ED061	camera, retinal, for remote imaging	NF		14	13	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
92229	Img rta detc/mntr ds poc aly	EF030	table, motorized (for instruments-equipment)	NF		14	13	E15: Refined equipment time to conform to changes in clinical labor time	0.00
93241	Ext ecg>48hr<7d rec scan a/r	ED021	computer, desktop, w-monitor	NF		100	95	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
93243	Ext ecg>48hr<7d scan a/r	ED021	computer, desktop, w-monitor	NF		100	95	E15: Refined equipment time to conform to changes in clinical labor time	-0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93245	Ext ecg>7d<15d rec scan a/r	ED021	computer, desktop, w-monitor	NF		128	123	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
93247	Ext ecg>7d<15d scan a/r	ED021	computer, desktop, w-monitor	NF		128	123	E15: Refined equipment time to conform to changes in clinical labor time	-0.03

TABLE 31: CY 2021 Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
67028, 92352, 92353	phenylephrine 2.5% ophth (Mydfrin)	SH056	$3.77	$5.46	45%	2	3,080,085
76510, 76512, 76513, 76529	ultrasonic biometry, B-scan	EQ247	$14,655.63	$26,647.50	82%	2	204,408
77401	Superficial radiation therapy system	ER045	$201,875.00	$204,999.67	2%	3	206,144
91200	Fibroscan with printer	ER101	$130,425.22	$125,096.21	-4%	6	30,527
G0166	EECP, external counterpulsation system	EQ012	$120,954.23	$111,128.30	-8%	2	88,907
G2082	Esketamine (56 mg vial)	SH109	$590.02	$616.93	5%	1	0
G2083	Esketamine (84 mg vial)	SH110	$885.02	$928.38	5%	1	0
34 codes	electrosurgical generator, gastrocautery	EQ113	$11,375.00	$36,180.00	218%	4	-
90 codes	endoscope disinfector, rigid or fiberoptic, w-cart	ES005	$36,556.97	$27,500.00	-25%	3	-
254 codes	scope video system (monitor, processor, digital capture, cart, printer, LED light)	ES031	$36,306.00	$70,673.38	95%	37	-
363 codes	suction machine (Gomco)	EQ235	$779.61	$3,195.85	310%	4	-
373 codes	mask, surgical	SB033	$0.15	$0.43	181%	259	-
851 codes	mask, surgical, with face shield	SB034	$1.24	$3.40	174%	49	-

TABLE 32: CY 2021 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
30468	Absorabable nasal implant and delivery device	SA133	1,995.00	1	9
32408	Coaxial Biopsy Set	SC108	49.00	1	1,324
32408	Pleural Plug kit	SA132	315.00	1	1,324
37238, 37239	venous stent system	SD340	1,750.00	10	6,592
57465	computer aided spectral imaging system (colposcopy)	ER117	32,000.00	1	79
57465	digital imaging speculum	SD337	5.80	1	79
67028	povidone soln (Betadine), single-use dropper	SJ094	2.31	1	3,080,085
67028	needle, 32g	SC109	0.59	3	3,080,085
69705, 69706	kit, eustachian tube procedure	SA134	2,010.00	7	74
69705, 69706	eustachian tube balloon	SD338	83.01	8	74
76145	Radiation Dosimetry Kit	EQ401	17,182.50	2	7,178
76513	Ophthalmic Ultrasound Biomicroscope (UBM Probe)	ER118	10,995.00	1	14,581
76513	ClearScan ultrasound water-filled condom probe cover	SB055	10.50	1	14,581
77401	Lead Room	ER119	17,236.00	1	206,144
77401	Lead Blocking Shield Kit	ER120	3,348.06	1	206,144
77520, 77522, 77523, 77525	Proton Treatment Vault	ER115	19,001,914.00	1	77,768
77520, 77522, 77523, 77525	Proton Treatment Delivery System	ER116	30,400,000.00	1	77,768
92227, 92228, 92229	camera, retinal, for remote imaging	ED061	14,156.68	3	2,391
92517, 92518, 92519	VEMP module	ED062	2,000.00	1	254
92584	ECochG electrode	SD335	24.21	1	10,213
92650	AABR-automated auditory brainstem response screening system	EQ396	20,000.00	1	0
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	-	0	229,813
94619, 94617, 94010, 94060	PFT System with PC and printer	EQ397	37,527.15	1	1,688,997
95012	sensor, filter, mouthpiece, nitric oxide	SD336	10.33	10	126,914
95012	monitoring system, nitric oxide	EQ398	1,500.00	4	126,914
99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215	Portable stand-on scale	EF048	1,343.85	1	204,303,328

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
G0166	EECP compression equipment package	SD341	826.75	17	88,907
G0166	EECP electrical equipment package	SD342	752.00	1	88,907
G0452	Sequence data analytics (alignment/variant calling) and reporting software	ED063	28,800.00	1	0
	3C patch system	SD343	625.00	2	104
	Mask, N95	SD344	2.36	94	0

TABLE 33: CY 2021 No PE Refinements

HCPCS	Description
10004	Fna bx w/o img gdn ea addl
10006	Fna bx w/us gdn ea addl
10008	Fna bx w/fluor gdn ea addl
10010	Fna bx w/ct gdn ea addl
10011	Fna bx w/mr gdn 1st les
10012	Fna bx w/mr gdn ea addl
11960	Insert tissue expander(s)
11970	Rplcmt tiss xpndr perm implt
11971	Rmvl tis xpndr wo insj implt
19307	Mast mod rad
19316	Suspension of breast
19318	Breast reduction
19325	Breast augmentation w/implt
19328	Rmvl intact breast implant
19330	Rmvl ruptured breast implant
19340	Insj breast implt sm d mast
19342	Insj/rplcmt brst implt sep d
19357	Tiss xpndr plmt brst rcnstj
19370	Revj peri-implt capsule brst
19371	Peri-implt capslc brst compl
19380	Revj reconstructed breast
27130	Total hip arthroplasty
27447	Total knee arthroplasty
29822	Sho arthrs srg lmtd dbrdmt
29823	Sho arthrs srg xtnsv dbrdmt
30468	Rpr nsl vlv collapse w/implt
32408	Core ndl bx lng/med perq
33741	Tas congenital car anomal
33745	Tis crtj cgen car anomal 1st
33746	Tis crtj cgen car anomal ea
33990	Insj perq vad l hrt arterial
33991	Insj perq vad l hrt artl&ven
33992	Rmvl perq left heart vad
33993	Reposg perq r/l hrt vad
33995	Insj perq vad r hrt venous
33997	Rmvl perq right heart vad
43239	Egd biopsy single/multiple
45385	Colonoscopy w/lesion removal
55880	Abltj mal prst8 tiss hifu
57282	Colpopexy extraperitoneal
57283	Colpopexy intraperitoneal
57425	Laparoscopy surg colpopexy
57465	Cam cervix uteri drg colp
69705	Nps surg dilat eust tube uni
69706	Nps surg dilat eust tube bi
70030	X-ray eye for foreign body
70450	Ct head/brain w/o dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
71250	Ct thorax dx c-
71260	Ct thorax dx c+
71270	Ct thorax dx c-/c+
75820	Vein x-ray arm/leg
75822	Vein x-ray arms/legs
75984	Xray control catheter change
76145	Med physic dos eval rad exps
77520	Proton trmt simple w/o comp
77522	Proton trmt simple w/comp
77523	Proton trmt intermediate
77525	Proton treatment complex
91200	Liver elastography
92227	Img rta detcj/mntr ds staff
92228	Img rta detc/mntr ds phy/qhp
92517	Vemp test i&r cervical
92518	Vemp test i&r ocular
92519	Vemp tst i&r cervical&ocular
92584	Electrocochleography
92650	Aep scr auditory potential
92651	Aep hearing status deter i&r
92652	Aep thrshld est mlt freq i&r
92653	Aep neurodiagnostic i&r
93000	Electrocardiogram complete
93005	Electrocardiogram tracing
93010	Electrocardiogram report
93224	Ecg monit/reprt up to 48 hrs
93225	Ecg monit/reprt up to 48 hrs
93226	Ecg monit/reprt up to 48 hrs
93227	Ecg monit/reprt up to 48 hrs
93242	Ext ecg>48hr<7d recording
93244	Ext ecg>48hr<7d rev&interpj
93246	Ext ecg>7d<15d recording
93248	Ext ecg>7d<15d rev&interpj
93306	Tte w/doppler complete
93750	Interrogation vad in person
94010	Breathing capacity test
94060	Evaluation of wheezing
94617	Exercise tst brncspsm w/ecg
94618	Pulmonary stress testing
94619	Exercise tst brncspsm wo ecg
94621	Cardiopulm exercise testing
94640	Airway inhalation treatment
94667	Chest wall manipulation
94668	Chest wall manipulation
94669	Mechanical chest wall oscill
95012	Exhaled nitric oxide meas
99439	Chrnc care mgmt svc ea addl
G0452	Molecular pathology interpr

BILLING CODE 4120–01–C

I. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. We are monitoring Medicare enrollment by OTPs and utilization of the new benefit to ensure that Medicare beneficiaries have appropriate access to care. For CY 2021, we proposed several refinements and also provided clarification of certain issues that stakeholders have brought to our attention.

2. Definition of OUD Treatment Services

In the CY 2020 PFS final rule (84 FR 62631 through 62635), we finalized a definition of ''OUD treatment services'' that reflects the statutory definition in section 1861(jjj)(1)(A) of the Act, which defines covered OUD treatment services to include oral, injected, and implanted opioid agonist and antagonist treatment medications approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for use in the treatment of OUD. There are three drugs currently approved by FDA for the treatment of opioid dependence: Buprenorphine; methadone; and naltrexone. In the CY 2020 PFS final rule, we noted that we had received comments supporting the proposed definition of OUD treatment services but also requesting that CMS include naloxone to treat opioid overdose in that definition as a medication used in treatment of OUD. Although we did not finalize including naloxone in the definition of OUD treatment services in that final rule, we indicated that as we continue to work on refining this new Medicare benefit, we would consider including additional drugs in the definition of OUD treatment services under our discretionary authority in section 1861(jjj)(1)(F) of the Act to include other items and services the Secretary determines are appropriate. As explained in the CY 2021 PFS proposed rule (85 FR 50203), we determined, after further consideration, that it would be appropriate to propose to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, that are approved by FDA under section 505 of the FFDCA for emergency treatment of opioid overdose.

Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.[28] [29] Naloxone should be given to a person who shows signs of an opioid overdose or when an overdose is suspected. FDA-approved naloxone products for overdose reversal are effective in reversing opioid overdose, including fentanyl-involved opioid overdoses, although overdoses involving potent (for example, fentanyl) or large quantities of opioids may require higher-than-normal doses of naloxone or repeated administration to reverse overdose.[30]

Naloxone attaches to opioid receptors and reverses and blocks the effects of other opioids.[31] FDA has approved injectable naloxone, intranasal naloxone, and naloxone auto-injector as emergency treatments for opioid overdose. The nasal spray is a prefilled, needle-free device that requires no assembly and can deliver a single dose into each nostril with two sprays. The auto-injector is injected into the outer thigh to deliver naloxone to the muscle (intramuscular). Both the nasal spray and naloxone auto-injector are packaged in a carton containing two doses to allow for repeat dosing if needed.[32] [33] These forms of naloxone can easily be administered by persons who do not have medical training and they may be prescribed to a patient who is receiving medication-assisted treatment (MAT) for OUD, especially if the patient is considered to be at risk for opioid overdose.[34] However, it is important to understand how to administer naloxone properly. A doctor or pharmacist can show patients, their family members, or caregivers how to administer naloxone.[35] We expect that a treating practitioner that is prescribing naloxone will also educate the patient, as appropriate, on how to administer the specific form of naloxone prescribed.

The U.S. Surgeon General Jerome M. Adams, M.D., M.P.H. has released a public health advisory stating that, ''Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities. Therefore, increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.'' [36]

In the CY 2021 PFS proposed rule, we proposed to add naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and to allow OTPs to be paid under Medicare for dispensing naloxone to Medicare beneficiaries who are receiving other OUD treatment services from the OTP. Under the proposal, beneficiaries receiving OUD treatment services from the OTP would be able to receive naloxone from the OTP under the OUD treatment services benefit, to the extent it is medically reasonable and necessary as part of their OUD treatment. We noted that naloxone is already covered under Medicare Part D. In 2017, 72.5 percent of all Medicare beneficiaries were enrolled in Medicare Part D plans.[37] However, as we explained in the proposed rule, we believe allowing beneficiaries to access this important emergency treatment at the OTP may help to decrease barriers to access because there currently are no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone.

Accordingly, to align with efforts to end the opioid epidemic, under the discretionary authority in section

[28] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.*

[29] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209862lbl.pdf.*

[30] *https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.*

[31] *https://www.drugabuse.gov/publications/drugfacts/naloxone.*

[32] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.*

[33] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209862lbl.pdf.*

[34] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone.*

[35] *https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/naloxone.*

[36] *https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.*

[37] *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.*

1861(jjj)(1)(F) of the Act, we proposed to amend the definition of OUD treatment services at § 410.67(b) by adding § 410.67(b)(8) to include opioid antagonist medications that are approved by FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose. We proposed to amend the definition of OUD treatment services under the discretionary authority in section 1861(jjj)(1)(F) of the Act rather than the authority under section 1861(jjj)(1)(A) of the Act because section 1861(jjj)(1)(A) of the Act pertains to opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by FDA under section 505 of the FFDCA for use in the treatment of opioid use disorder. As we explained in the CY 2021 PFS proposed rule, naloxone is not one of the three drugs currently approved by FDA for the treatment of opioid dependence (buprenorphine, methadone, and naltrexone);[38] and, as a result, we do not believe naloxone fits the criteria of section 1861(jjj)(1)(A) of the Act. We sought comment on our proposal to expand the definition of OUD treatment services.

Additionally, we noted that we agree with the public health advisory quoted previously that community education related to overdose prevention is needed to address the opioid crisis. We believe that prevention and community education efforts would increase awareness of treatment options and could play a role in decreasing opioid overdose deaths. We solicited comments on whether the definition of OUD treatment services should be further revised to include overdose education. Additionally, we also solicited comments on whether payment for providing overdose education to the beneficiary and/or the beneficiary's family or partner should be considered to be included in the current weekly bundled payments for episodes of care or whether we should consider establishing an add-on payment for education related to overdose prevention when such services are furnished by OTPs. We specifically sought information related to what inputs we might consider in developing the payment rate for such a service, such as payment amounts for similar services under the PFS, if we were to include this type of education as part of the proposed new add-on codes for naloxone discussed later in this section (HCPCS codes GOTP1 and GOTP2), For example, in order to establish a payment rate for education related to overdose prevention for the beneficiary and/or the beneficiary's family or partner, we could consider a crosswalk to the Medicare payment rate for CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument).* The current non-facility payment rate under the PFS for CPT code 96161 is $2.53.

a. Adjustment to the Bundled Payments for OUD Treatment Services

Consistent with the proposal to expand the definition of OUD treatment services to include opioid antagonist medications indicated for the emergency treatment of known or suspected opioid overdose, we noted that we believed it would be appropriate to propose changes to the payment rates for the bundled payments to reflect the costs of these medications. Therefore, we proposed to adjust the bundled payment rates through the use of add-on codes to account for instances in which OTPs provide Medicare beneficiaries with naloxone. We explained that we believe beneficiaries receiving naloxone will need a supply at the start of treatment and would only require refills later if the supply is used in an emergency. As a result, we noted that we would not expect naloxone to be provided weekly to all patients, but only on an as-needed basis. Accordingly, we noted that we believed that making payment for naloxone through the use of an add-on code would be the most accurate approach to pricing rather than including the costs of these medications as part of the bundled payment rates for all episodes of care.

We proposed to adopt the following add-on G codes:

- *HCPCS code GOTP1:* Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- *HCPCS code GOTP2:* Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

We proposed to adopt an approach similar to the pricing methodology that was used to price the drug component of the bundled payments in the CY 2020 PFS final rule to determine the payment rate for these proposed new add-on codes for naloxone. In the CY 2020 PFS proposed rule (84 FR 40530), we explained that payment structures that are closely tailored to the provider's actual acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. Therefore, we noted that we believe it would be appropriate to use a methodology similar to the one we adopted in the CY 2020 PFS final rule (84 FR 62650 through 62657), for purposes of determining the payment rate for the drug component of the bundled payments to determine the payment rates for the add on codes for naloxone because this methodology would provide the best estimate of an OTP's cost in dispensing naloxone.

In the CY 2020 PFS final rule, we adopted a policy under which we apply the methodology set forth in section 1847A of the Act to determine the payment amount for the drug component of the bundled payment for an episode of care that includes implantable or injectable medications, except that the payment amount shall be 100 percent of the average sales price (ASP), if ASP is used. For oral medications, the payment for the drug component is based on 100 percent of ASP, if ASP data are available. However, if ASP is not available, the payment amount for methadone will be based on the TRICARE rate and the payment amount for oral buprenorphine is calculated using the national average drug acquisition cost (NADAC).

We received public comments on the proposed adjustment to the bundled payments for OUD treatment services to account for instances in which OTPs provide Medicare beneficiaries with naloxone. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of extending the definition of OUD treatment services to include opioid antagonist medications, such as naloxone.

Response: We thank commenters for their support of extending the definition of OUD treatment services to include opioid antagonist medications, such as naloxone. Because we continue to believe that the availability of emergency treatment medications is an important component of treatment for OUD, we are finalizing our proposal to amend the definition of OUD treatment service in § 410.67 to add paragraph (b)(8) to include opioid antagonist medications approved by the FDA under section 505 of the FFDCA for emergency treatment of known or suspected opioid overdose.

[38] *https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat.*

Comment: Overall, commenters were in support of revising the definition of OUD treatment services to include overdose education. Several commenters indicated that overdose education should be included in the currently established bundled payment. Some other commenters suggested creating a separate add-on code and payment for providing overdose prevention education. Some commenters supported including community education for naloxone as an add-on service, but disagreed with the example provided in the proposed rule (85 FR 50203 and 50204) of using the CY 2020 Medicare payment rate for CPT code 96161 of $2.53 to determine the additional payment amount. Rather, a commenter stated that CPT code 96161 is not commensurate with the cost of the service nor reflective of the required staff involvement and overhead cost and recommended a payment rate of $20 at 15-minute increments. While another commenter thought the clinical activities are more aligned with 98960 (*Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient*). Another commenter indicated that overdose education was proposed for Medicare Part D plans for contract year 2021 as part of Medication Therapy Management (MTM) and Drug Management Programs (DMP). However, no additional payment was proposed for these services when delivered in Medicare Part D. Another commenter stated that all patients receiving treatment at an OTP as well as their families should receive overdose education and urged CMS to include this payment in the add-on payments for intake activities and periodic assessments, and in the bundled payment for the initial month of substance use disorder treatment. One commenter stated that the availability of naloxone and other medications that can rapidly reverse an opioid overdose, along with education on its proper use, will save lives. The commenter also recommended that, whether reimbursement for overdose education is included as part of the bundled payment or billed as an add-on service, CMS include guardrails on what services OTPs are permitted to code as education to prevent waste and abuse, including specific requirements regarding the quality of services.

Response: After consideration of comments, we are revising the definition of OUD treatment services to include overdose education. We continue to agree with the U.S. Surgeon General's public health advisory discussed above that community education related to overdose prevention is needed to address the opioid crisis. Overdose education includes educating patients and caregivers on how to recognize respiratory depression, the signs and symptoms of a possible opioid overdose, how to administer naloxone in the event of an overdose, and the importance of calling 911 or getting emergency medical help right away, even if naloxone is administered.[39] Providing naloxone and teaching people to use it is an effective means of preventing deaths among people who misuse opioids. With brief training, most adults can learn to administer life-saving naloxone.[40] We are modifying the proposed provision at § 410.67(b)(8) to include a reference to overdose education that is furnished in conjunction with opioid antagonist medications. After considering the commenters' recommendations regarding the payment rate for this type of education, which ranged from a payment rate of $20 for each 15 minutes of education, to no separate payment for this education, we have determined that it would be appropriate to use a crosswalk to the CY 2020 Medicare payment rate for CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument),* which is assigned a non-facility payment rate under the PFS of $2.53. We believe this reference code describes a similar level of service intensity and amount of clinical staff time involved in furnishing overdose education. We believe establishing a separate add-on code for overdose education to be billed in 15-minute increments is unnecessary and may result in overpayment for this service. As noted in the CY 2017 PFS final rule (81 FR 80331), we recognize that practitioners' interactions with caregivers or family members are an integral part of treatment for some patients. Overdose education and naloxone distribution programs have reduced opioid-related overdose for over 20 years.[41] Therefore, as naloxone and overdose education complement one another, we are finalizing add-on codes for naloxone that consist of both a drug component and a non-drug component that would account for overdose education furnished by the OTP. Therefore, the overdose education add-on will be included each time naloxone is furnished by the OTP. We will consider for future rulemaking whether separate coding is needed to allow payment for overdose education when it is furnished separate from the OTP furnishing the patient with naloxone.

Comment: Several commenters were in support of creating a new code for auto-injector naloxone and nasal naloxone. One commenter stated that the generic version of the auto-injector naloxone is currently not available in the marketplace.

Response: We thank the commenters for their support for creating new codes for the auto-injector naloxone and nasal naloxone. After consideration of the comments, we are finalizing our proposal to establish an add-on code for nasal naloxone that is dispensed in conjunction with an episode of care for treatment of OUD. We believe establishing an add-on code for nasal naloxone to allow OTPs to receive payment when they dispense this medication will allow beneficiaries access to this important emergency treatment at OTPs and may help decrease barriers to access because there are currently no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone. We note that both the brand and authorized generic formulation of the auto-injector naloxone have been discontinued with obsolete dates effective September 4, 2020.[42] Therefore, we are not finalizing our proposal to create an add-on code for auto-injector naloxone.

After consideration of comments, we are extending the definition of OUD treatment services to include short acting opioid antagonist medications, such as naloxone. We are further revising the definition of OUD treatment services to include overdose education furnished in conjunction with providing an opioid antagonist medication. We are also finalizing our proposal to create a code for nasal naloxone: HCPCS code G2215 (*Take-home supply of nasal naloxone (provision of the services by a*

[39] *https://www.fda.gov/media/140360/download#:~:text=%E2%80%A2%20Naloxone%20is%20an%20FDA-approved%20medicine%20used%20to,Signs%20of%20an%20opioid%20overdose%20include%20breathing%20problems%2C.*

[40] *https://www.samhsa.gov/homelessness-programs-resources/hpr-resources/useful-resources-opioid-overdose-prevention.*

[41] *https://www.japha.org/article/S1544-3191(17)30002-X/fulltext.*

[42] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209862.*

Medicare-enrolled Opioid Treatment Program)); List separately in addition to code for primary procedure.), which will include both a drug component and a non-drug component for overdose education. The payment for the non-drug component of this code will be determined using a crosswalk to the Medicare payment rate for CPT code 96161 of $2.53.

Drug Pricing for Nasal Naloxone

Consistent with the approach that we adopted for pricing the drug component of the weekly bundled payments, we proposed to price the add-on code describing the take home supply of nasal naloxone, using the same methodology we previously adopted for pricing the drug component of episodes of care that include implantable or injectable medications. Accordingly, the payment methodology would be based upon the methodology set forth in section 1847A of the Act, except that payment amounts determined based on ASP and wholesale acquisition cost (WAC) would not include any add-on percentages. In the CY 2021 PFS proposed rule (85 FR 50204), we acknowledged that nasal naloxone is not an oral, implantable or injectable medication; however, ASP data are available. We explained that, as noted in the CY 2020 PFS final rule (84 FR 62653), we believe using ASP provides a transparent and public benchmark for manufacturers' pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions as noted in section 1847A(c)(2) of the Act) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Therefore, we believe ASP to be the most market-based approach to set drug prices. We sought public comment on our proposal to use ASP+0 to price the add-on payment for nasal naloxone and other potential sources of pricing data for nasal naloxone either generally or specifically with respect to acquisition by OTPs.

We received public comments on the proposed drug pricing for nasal naloxone. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed the proposed ASP + 0 payment for nasal naloxone and asserted that if payment for nasal naloxone is below cost, OTPs would not be able to offer this medication to Medicare beneficiaries. A commenter indicated that this product is made by one manufacturer that does not offer volume discounts. Commenters generally recommended including an add-on payment similar to other drugs. A couple of commenters stated that the cost for OTPs to purchase nasal naloxone is $125. Accordingly, they recommended a payment of cost + 6 percent for nasal naloxone ($125 + 6 percent). A commenter indicated the cost + 6 percent payment rate would avoid imposing a financial loss on OTPs for providing naloxone and take into account OTP overhead costs (for example, training, security), thereby encouraging OTPs to provide this critical medication. A few commenters were in support of the proposed ASP + 0 payment for nasal naloxone. One commenter agreed that setting the payment rate for nasal naloxone at ASP is a reasonable approach.

Response: After review of the comments, we are finalizing our proposal to apply the payment methodology set forth in section 1847A of the Act to determine the payment for the nasal naloxone. However, as proposed, payment amounts for nasal naloxone, determined based on ASP and wholesale acquisition cost (WAC) will not include any add-on percentages. The use of ASP provides a transparent and public benchmark for the acquisition cost of a drug as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. We believe this approach is most consistent with the approach we adopted in the CY 2020 PFS final rule for pricing the drug component of an episode of care that includes implantable or injectable medications. For the reasons discussed in the CY 2020 PFS final rule (84 FR 62652 and 62653), we continue to believe that limiting the payment amount to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for a HCPCS code will incentivize the use of the most clinically appropriate drug for a given patient. We understand that many OTPs purchase medications directly from drug manufacturers, thereby limiting the markup from distribution channels. We continue to believe that the selection of drugs purchased by most OTPs is quite limited, which theoretically limits the utility of third-parties, such as wholesalers, and their associated costs and increases the purchase volume for OTPs and accompanying manufacturer discounts. We believe that this situation could lend itself to an OTP drug channel for purchasing at discounted rates either directly or through the use of buying groups as is the standard in the pharmacy industry today. We believe that our proposed approach of paying for nasal naloxone based on ASP offers the most appropriate balance between ensuring OTPs receive appropriate reimbursement for their drug acquisition costs, while also preserving the incentive to use the most clinically appropriate drug for the treatment of individual beneficiaries.

We are interested in continuing to obtain feedback regarding access concerns related to naloxone payment. We will monitor utilization of these codes in the claims data to determine whether CMS should consider proposing changes in the future to the payment policies finalized in this rule.

Drug Pricing for Auto-Injector Naloxone

We proposed to price the add-on code describing the take-home supply of auto-injector naloxone, using the lowest pricing available (the lower of ASP + 0, WAC + 0, or NADAC). Currently, there is no ASP or NADAC reported or calculated for auto-injector naloxone. Accordingly, we proposed to use WAC + 0 to determine the pricing for the add-on payment for auto-injector naloxone. We explained that we believe 100 percent of WAC is a closer estimate of the actual acquisition cost for OTPs compared to WAC with an add-on percentage because, as defined in section 1847A(c)(6)(B) of the Act, WAC does not include prompt pay discounts, rebates or reductions in price. Thus, there should be no need to pay an add-on percentage to ensure OTPs are reimbursed for their acquisition costs for auto-injector naloxone. However, we also noted that in the future, using the lowest pricing available for auto-injector naloxone may be most appropriate, because if ASP and/or NADAC pricing were to become available for auto-injector naloxone, they would be more reflective of actual costs than a list price.

We noted that auto-injector naloxone was available in both a generic and brand name version. We explained that we had considered comparing the Medicare Part D utilization for each formulation to determine the frequency with which the generic and brand name versions might dispensed by OTPs. However, because the generic auto-injector naloxone was rather new to the marketplace [43], we acknowledged that there were limited utilization data available for the generic product. Based on historical information reflecting a

[43] *https://kaleo.com/in-the-news/authorized-generic-for-evzio-naloxone-hcl-injection-to-be-available-at-a-reduced-list-price-of-178/.*

trend of increased generic utilization uptake,[44] we explained that we believed that in most cases where the auto-injector naloxone would be prescribed and dispensed by OTPs to beneficiaries, it would be the generic formulation of the product. Therefore, we noted that we believed using the price for the generic formulation would be a reasonable approach to pricing the proposed add-on code for auto-injector naloxone and would ensure that beneficiaries who need this drug as part of their treatment for OUD would have access to it and that OTPs would receive a reasonable payment for dispensing the drug. Accordingly, we proposed to use the price of the generic formulation, determined as WAC + 0, to pay for auto-injector naloxone when the drug is provided by an OTP as part of an episode of care. We sought comment on our proposed pricing methodology to pay for auto-injector naloxone and other potential sources of pricing data for auto-injector naloxone either generally or specifically with respect to acquisition by OTPs.

We received public comments on the proposed drug pricing for auto-injector naloxone. The following is a summary of the comments we received and our response.

Comment: One commenter pointed out that generic auto-injector naloxone is not currently available in the marketplace and stated that the brand name auto-injector naloxone costs about $4,000. The commenter stated that the proposed payment rate for auto-injector naloxone is inadequate and should be revised to accurately reflect the true acquisition cost of the drug. Another commenter recommended a payment rate of cost plus 6 percent for auto-injector naloxone. Some other commenters also recommended including an add-on of plus 6 percent to the payment rate, similar to other drugs.

Response: As previously discussed, both the brand name auto-injector (Evzio) and authorized generic naloxone auto-injector were recently discontinued with obsolete dates effective September 4, 2020. Because auto-injector naloxone is no longer available in the marketplace, we are not finalizing the proposed code and pricing for auto-injector naloxone.

Frequency Limit

In the CY 2021 PFS proposed rule (85 FR 50205), we noted that Medicare Part D allows prescription drug plans to place quantity limits (QL) on most drugs, including on naloxone. While most Medicare Part D plans do not limit the amount of naloxone a beneficiary is able to receive in a given month, when they do, they most frequently allow a plan enrollee a maximum of 4 units per 30 days (2 boxes of 2 units). In the current contract year (2020) only 22 percent of Medicare Part D formularies apply a QL to naloxone (115/535 formularies), while for the 2021 contract year only 19 percent of Medicare Part D formularies plan to apply a QL to this product (106/564 formularies). However, a review of Medicare Part D claims data shows that beneficiaries who use naloxone most frequently use only one box (2 units) within a 30-day period even though nearly all plans would have permitted additional doses. We also noted that under TRICARE, auto-injector naloxone is covered for a maximum quantity of one carton at retail network pharmacies for up to a 30-day supply.[45] We explained our belief that it would be appropriate to apply a similar limit on the frequency of the add-on payment for naloxone dispensed by OTPs. We stated that applying a frequency limit would assist in enhancing patient safety and discourage misuse, waste and abuse. Furthermore, we noted that such a limitation was reasonable because there are other services that OTPs should already be performing, and which are already included in the weekly bundled payments for episodes of care, such as counseling and individual and group therapy, that should limit the need for this emergency treatment. However, we noted that we do not want to limit access to naloxone when it is a medically reasonable and necessary part of the treatment for OUD. Therefore, we proposed to limit Medicare payment to OTPs for naloxone to one add-on code (HCPCS code GOTP1 or GOTP2) every 30 days to the extent that it is medically reasonable and necessary. We sought comment on whether this proposed limit was reasonable and whether special circumstances may arise under which more frequent payment would be medically reasonable and necessary and the types of circumstances that should qualify for more frequent payment. However, we noted that we also expect OTPs and their treating practitioners will use their clinical judgment as to whether there may be cases in which a referral to a higher level of care may be needed for some beneficiaries in order to reduce the risk of overdose and the need for more frequent emergency treatment. We proposed to add § 410.67(d)(4)(i)(E) to describe payment for a take-home supply of opioid antagonist medications that are approved by FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose.

We invited public comments on the proposed pricing for nasal naloxone and auto-injector naloxone. We also sought comment on the proposal to limit payment for the proposed add-on codes for take-home supplies of these medications to once every 30 days to the extent that it is medically reasonable and necessary.

We received public comments on the proposed frequency limit. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support imposing frequency limits on the provision of naloxone to once per month and stated that clinicians should determine medical necessity, noting that naloxone is a life-saving drug and patient access should not be limited. One commenter recommended that exceptions be allowed for patients with a recent (within the last 30 days) overdose. Other commenters supported the proposed frequency limit and found it reasonable.

Response: After consideration of the comments, we are finalizing a frequency limit on Medicare payments to OTPs for naloxone to one add-on code (HCPCS code G2215 or G2216) every 30 days. However, we agree with commenters that access to naloxone should not be limited when it is a medically reasonable and necessary part of the treatment for OUD. Therefore, we will allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of naloxone dispensed by the OTP to the extent that it is medically reasonable and necessary to furnish additional naloxone. We note that section 1862(a)(1)(A) of the Act requires that in order for payment to made for most Part A and Part B services furnished to Medicare beneficiaries, those services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the malfunctioning of a malformed body member. If an additional supply of naloxone is needed within 30 days of the original supply being provided, OTPs must document in the medical record the reason for the exception. Additionally, CMS will monitor utilization of these codes in the claims data and will refer cases of disproportionate use for further review.

Additionally, we sought comment on whether we should consider creating a

[44] In 2015, approximately 87 percent of prescriptions filled under Part D were for generic drugs, compared with 61 percent in 2007. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.*

[45] *https://www.express-scripts.com/static/formularySearch/2.9.6/#/formularySearch/drugSearch.*

code and establishing an add-on payment for injectable naloxone. We noted that all three forms of naloxone (injectable, auto-injector, and nasal spray) are FDA-approved and may be considered as options for community distribution.

It is important to understand how to administer naloxone properly, therefore, we defer to the clinical judgment of practitioners in the OTP as to which formulation of naloxone would be the most appropriate to dispense to a patient. Brief education on how to administer naloxone using a syringe can be obtained from the provider of the naloxone kit or from *http://prescribetoprevent.org/*.[46] Additionally, we note that in this final rule, we are including overdose education in the non-drug component of the payment rate for both of the new add-on codes for naloxone (HCPCS codes G2215 and G2216), and expect that when OTPs provide beneficiaries with a supply of naloxone, they will also inform them about how to use the medication they are being given.

We stated in the CY 2021 PFS proposed rule (85 FR 50205) that if we were to establish an add-on payment for injectable naloxone, we would consider using the same methodology we adopted for pricing the drug component of an episode of care that includes implantable or injectable medications, as described in § 410.67(d)(2)(i)(A).

We received public comments in response to our request for input on whether we should create a code and establish an add-on payment for injectable naloxone. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the creation of coding and payment for injectable naloxone. Some commenters stated that ensuring payment for all three forms of FDA-approved naloxone would allow providers to select the most appropriate form of naloxone for the particular Medicare beneficiary and provide options in the case of drug shortages. The commenters also noted that traditionally, injectable naloxone is the least expensive form, but can be more difficult to administer in an overdose emergency. Another commenter stated that they believe formulations of naloxone that are intended for use by medical professionals (that is, injectable naloxone) are also valuable in the prevention and treatment of opioid overdose. The commenter stated that given that it is highly probable that OTP providers will be in a position to provide care to a beneficiary who has overdosed, the availability of injectable naloxone at these facilities can facilitate timely opioid overdose reversal. Some commenters stated that the payment rate for injectable naloxone must be adequate and another stated that they believe payment should align with payment for other Medicare Part B medications (that is, ASP plus 6 percent).

Response: We agree with the commenters that providing for Medicare payment to OTPs for all available forms of FDA-approved naloxone will allow practitioners in OTPs to select the most appropriate form of naloxone for the beneficiary, provide options in the case of drug shortages, and expand access to treatment for opioid overdoses. Although we acknowledge that individuals experiencing an opioid overdose will not be able to use injectable naloxone to treat an overdose themselves,[47] self-administration of naloxone is not necessarily a goal of overdose death prevention training. A safer, more reliable approach may be to prescribe naloxone to at-risk patients and train and also equip members of their household and social networks in overdose prevention and response.[48]

After consideration of the comments received, we are finalizing a second new add-on code to cover the cost of providing patients with a supply of injectable naloxone. We recognize the importance of making injectable naloxone available to Medicare beneficiaries. Additionally, creating a new add-on code for injectable and nasal naloxone will provide options in the case of drug shortages or in the event a drug is no longer available in the market, as occurred with auto-injector naloxone.

The add-on code for injectable naloxone is HCPCS code G2216 (*Take-home supply of injectable naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*), which will include both a drug component and a non-drug component. As stated in previous rulemaking (84 FR 62650), we use the typical maintenance dose to calculate the drug component for the OTP benefit. According to the package insert,[49] [50] an initial dose of 0.4 mg to 2 mg of injectable naloxone may be administered through intravenous, intramuscular, or subcutaneous routes. If needed, it may be repeated at two- to three-minute intervals up to a total dose of 10mg. Because the information we have is not based upon a typical dose, we are contractor pricing this code for CY 2021. This will provide beneficiaries access to injectable naloxone under the OTP benefit and will also allow us the opportunity to obtain more information to better understand the typical dosage of injectable naloxone, in order to potentially establish national pricing for injectable naloxone through future rulemaking. The payment for the non-drug component of this code will be determined using a crosswalk to the Medicare payment rate for CPT code 96161 of $2.53, as discussed previously in conjunction with the new code for nasal naloxone (HCPCS G2215).

Table 34 details the new add-on codes for nasal naloxone and injectable naloxone, and the accompanying payment amounts, which reflect the cost of the drug plus an additional $ 2.53 for overdose education, as discussed previously in this section.

[46] *https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.*

[47] *https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/opioid-overdose.*

[48] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4019939/.*

[49] *http://labeling.pfizer.com/ShowLabeling.aspx?id=4541.*

[50] *https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f0932877-1f3b-4d5e-82d2-dd6c53db4730&type=display.*

TABLE 34: OTP Code Descriptors and Payment Amounts*

HCPCS	Descriptor	Total Payment
G2215	Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$92.13
G2216	Take-home supply of injectable naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	Contractor-priced

* Nasal naloxone drug costs are calculated using ASP data plus a payment of $2.53 for overdose education. HCPCS code G2216 will be contractor-priced and will also include a payment of $2.53 for overdose education.

Duplicative Payment

Section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. In the CY 2021 PFS proposed rule (85 FR 50206), we noted that under the proposal, OTPs would be able to provide naloxone to Medicare beneficiaries and bill for it as an add-on to the bundled payment for the episode of care. Consistent with § 410.67(e), the beneficiary's copayment amount would remain zero. We also noted that naloxone may also be appropriately available to beneficiaries through other Medicare benefits, including, for example, Medicare Part D, under which the beneficiary would be responsible for the applicable cost sharing. As discussed in the CY 2020 PFS final rule (84 FR 62664) and codified at § 410.67(d)(5), we define duplicative payment to involve only those circumstances where medications that are delivered, administered or dispensed to a beneficiary are paid as part of the OTP bundled payment, and where the delivery, administration or dispensing of the same medication (that is, same drug, dosage and formulation) is also separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Because we proposed to pay for naloxone as an add-on to the weekly bundled payment, any payment to an OTP for naloxone would be duplicative if the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Consistent with § 410.67(d)(5), CMS would recoup any duplicative payment made to an OTP for naloxone.

Additionally, we noted that we understand some OTPs negotiate arrangements whereby community pharmacies supply MAT-related medications to OTPs. However, we reiterated that, as stated in the CY 2020 PFS final rule, if the OTP provides reasonable and necessary MAT-related medications as part of an episode of care, we would expect the OTP to take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payment. Thus, naloxone billed by an OTP as an add-on to the bundled payment should not be reported to or paid under a Medicare Part D plan. We noted that we expect OTPs will take reasonable steps to prevent duplicative payment for naloxone furnished under their care by ensuring it is not reported or billed under a different Medicare benefit. We also noted that we intend to monitor for duplicative payments, and would take appropriate action as needed when and if such duplicative payments are identified.

We received public comments on the discussion of duplicative payment for naloxone. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed recoupment of duplicative payments made to OTPs for naloxone. One commenter noted that OTPs do not have the capacity to be aware of or prevent other providers from prescribing naloxone through Medicare Part D. A commenter recommended that CMS inform health plans if a member is receiving services from an OTP, but acknowledged this may be difficult due to privacy laws. A commenter stated that CMS should either establish a means of coordination or recoup payment from Medicare Part D plans and other healthcare providers if naloxone is provided outside of the OTP. Another commenter stated that if the proposal to establish an add-on payment for naloxone is finalized, CMS will need to provide instructions to guard against duplicative payment.

Response: As we are finalizing the proposal to pay for naloxone as an add-on to the weekly bundled payment, we reiterate that consistent with § 410.67(d)(5), any payment to an OTP for naloxone would be duplicative if a claim for the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service, and CMS would recoup any duplicative payment made to an OTP for naloxone. Section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. Therefore, for purposes of implementing section 1834(w)(1) of the Act, payment for medications delivered, administered or dispensed to the beneficiary as part of the OTP bundled payment is considered duplicative if delivery, administration or dispensing of the same medication was also separately paid under Medicare Part B or D. CMS would recoup any duplicative payment made to an OTP for naloxone because OTPs will be in the best position to know whether naloxone that is included as part of the beneficiary's treatment plan is being furnished by the OTP or by another provider or supplier given that the OTP is responsible for managing the beneficiary's overall OUD treatment. OTPs should make a good faith effort to ensure that no duplicative payments are made for naloxone, for example, by inquiring whether the beneficiary has already received a supply of naloxone through Medicare Part B or D. Please see the CY 2020 PFS final rule (84 FR 62663 and 62664) for a more detailed discussion of our policy on duplicative payments.

3. WAC Pricing

Section 1834(w) of the Act gives the Secretary significant discretion to establish bundled payment rates for OUD treatment services. In the CY 2020 PFS final rule, we finalized a payment methodology for the drug component of

the bundled payment rates for OUD treatment services, under which we use the payment methodology set forth in section 1847A of the Act (which bases most payment on ASP) to set the payment rates for implantable and injectable drugs and limited the payment amount for these drugs to 100 percent of the volume-weighted ASP for a drug category or code, if ASP is used. We codified this payment methodology at § 410.67(d)(2)(i)(A).

Section 1847A of the Act provides for the use of other payment methodologies in certain circumstances, including payment based on WAC or average manufacturer price (AMP). In the CY 2020 PFS final rule, we limited payments to OTPs for injectable and implantable drugs to 100 percent of ASP, but did not otherwise diverge from the payment methodology that would apply under section 1847A of the Act. In the CY 2021 PFS proposed rule (85 FR 50206), we noted our belief that it was necessary to amend the OTP drug pricing methodology in order to limit WAC-based payments to 100 percent of WAC. As discussed previously, we proposed to use WAC pricing to determine the payment rate for the add-on code for the auto-injector naloxone. Although none of the drugs that are currently included in the drug component of an episode of care is currently paid based on WAC, we also noted that it is possible that we may use WAC to determine the payment for the drug component of an episode of care in the future, and we wanted to establish, in advance, the methodology that would apply for purposes of determining the payment rate.

As authorized under section 1847A of the Act, some Medicare Part B drugs are paid based on WAC. For example, for single source drugs, payment is 106 percent of the lesser of WAC or ASP (section 1847A(b)(4) of the Act), and in cases where ASP is unavailable during the first quarter of sales (section 1847A(c)(4) of the Act), 103 percent of WAC is used. Additionally, there are some instances where drugs lack ASP data for reasons other than being new, for example, in cases where the manufacturer had no sales in a reporting quarter. In those situations, the Medicare payment method varies, but in some cases, the payment may be 106 percent of the WAC.[51] As we stated in the CY 2020 PFS final rule (84 FR 62651), payment structures that are closely tailored to the provider's actual acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. The WAC is defined in section 1847A(c)(6)(B) as the manufacturer's list price for a drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price. A drug's WAC is ultimately controlled by the manufacturer. Unlike ASP, a drug's WAC does not incorporate prompt-pay or other discounts. If discounts are available on drugs reimbursed by Medicare at 106 percent of WAC, then Medicare is paying more for drugs than it otherwise would under the ASP-based formula.[52] Therefore, consistent with our existing policy to set the payment amount at 100 percent of the ASP, if ASP is used to determine the payment for the drug component of an episode of care, we proposed that when WAC-based pricing is used, the payment amount shall be WAC + 0. We proposed to amend the provision at § 410.67(d)(2)(i)(A) to reflect this limitation.

We solicited comments on this proposed alternative pricing methodology when the payment for an implantable or injectable medication included in the drug component of an episode of care is determined using the methodology set forth in section 1847A of the Act, and ASP pricing data are not available.

We received public comments on the WAC pricing proposal. The following is a summary of the comments we received and our responses.

Comment: A commenter expressed concern with CMS establishing payment rates for medications that deviate from the standard methodology under Medicare Part B of paying for drugs at the current rate of ASP plus 6 percent. The commenter also stated that they were concerned that limiting payment to Wholesale Acquisition Cost (WAC) when ASP is not available would limit OTPs' ability to treat Medicare beneficiaries effectively. Another commenter supported the use of WAC + 0 and stated, in reference to auto-injector naloxone, that any payments above WAC would likely only serve to encourage price increases in the market more broadly.

Response: We thank the commenters for their feedback on our proposal that when the payment for an implantable or injectable medication included in the drug component of an episode of care is determined using the methodology set forth in section 1847A of the Act, and ASP pricing data are not available, and WAC-based pricing is used, the payment amount shall be WAC + 0. We continue to believe that payment structures that are closely tailored to the provider's acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. Because WAC does not include prompt pay discounts, rebates or price reductions, we believe WAC could be a much higher than acquisition cost. However, we continue to believe that 100 percent of WAC is a closer estimate of the actual acquisition cost for OTPs compared to WAC with an add-on percentage. Therefore, we are finalizing our proposal that when WAC-based pricing is used, the payment amount shall be WAC + 0. We are also finalizing the proposed amendment to the provision at § 410.67(d)(2)(i)(A) to reflect this pricing methodology.

4. Billing and Payment Policies

a. Institutional Claim Forms

As discussed in the CY 2021 PFS proposed rule (85 FR 50207), we have received several requests to allow OTPs to bill on an institutional claim form. We were informed by representatives from the state of New York that all OTPs in New York state bill on institutional claim forms, not just those that are part of a hospital system. Given the public health need related to the opioid epidemic, we explained that we were exploring claims processing flexibilities requested by some OTPs that would allow them to bill services on institutional claims. See also section III.B. of this final rule, OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions, for a discussion related to OTP enrollment as it relates to institutional claims. As we explained in the CY 2021 PFS proposed rule, there would be no differences in coverage or payment between services billed on the institutional claim form versus the professional claim form. We noted that the National Uniform Billing Committee (NUBC) approved a new Type Of Bill (087x) for Freestanding Non-residential Opioid Treatment Program provider billing, as well as a new condition code (89) for Opioid Treatment Program/Indicates claim for opioid treatment program services, to be used on hospital based OTP claims (TOB 013x and 085x). We sought information on the reasons this claims-processing flexibility is necessary for OTPs, and stated that we would address any changes to provider billing policies

[51] *http://www.medpac.gov/-blog-/requiring-reporting-of-sales-price-data/2019/06/14/payment-for-part-b-drugs.*

[52] *http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf.*

in subsequent claims processing instructions.

We received public comments on allowing OTPs to bill on an institutional claim form. The following is a summary of the comments we received and our response.

Comment: Several commenters expressed support for allowing this flexibility. One commenter noted that they anticipate there will be a significant increase in OTP enrollment as a result of this flexibility, especially in states that have a significant number of hospital-based OTPs. Another commenter noted that allowing OTPs to submit claims on the institutional claim form (837i) will help to facilitate the processing of crossover claims between Medicare and Medicaid.

Response: We are continuing to explore how best to implement these flexibilities. We will provide notice of any relevant changes through claims processing instructions.

b. Periodic Assessments

In the CY 2020 PFS final rule (84 FR 62634), we stated that we understood that intake activities and periodic assessments are integral services for the establishment and maintenance of OUD treatment for a beneficiary at an OTP, and therefore, we believed it was reasonable to include these services in the definition of OUD treatment services. Accordingly, we finalized a definition of OUD treatment services in § 410.67(b) that reflected the required intake activities and periodic assessments. We stated it was our understanding that these services are furnished much less frequently than the other services included in the weekly bundled payments; therefore, we created add-on G codes to describe these services, which would allow us to make more targeted payments for these services. We noted that the add-on code describing intake activities should only be billed for new patients (that is, patients starting treatment at the OTP). We agreed with the commenters that the level 4 office/outpatient E/M visits for new and established patients are a good approximation of the services provided at intake and during periodic assessments at OTPs based on the expected acuity of patients with OUD receiving services at OTPs, who are likely to have multiple co-morbidities and present with problems that are of moderate to high severity and require medical decision making of moderate complexity. The finalized add-on codes are HCPCS code G2076 (*Intake activities; including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized health care professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel*) and HCPCS code G2077 (*Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment*). The medical services described by these add-on codes can be furnished by a program physician, a primary care physician or an authorized healthcare professional under the supervision of a program physician or qualified personnel such as nurse practitioners (NPs) and physician assistants (PAs). The other assessments, including psychosocial assessments can be furnished by practitioners who are eligible to do so under state law and their scope of licensure. We noted that to bill for the add-on code, the services need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record (84 FR 62647).

As we explained in the CY 2021 PFS proposed rule (85 FR 50207), we have received inquiries from stakeholders related to what activities would qualify to bill the add-on code for periodic assessments, HCPCS code G2077. In the CY 2020 PFS final rule (84 FR 62647), we noted that the add-on code describing periodic assessments can be billed for each periodic assessment performed for patients that require multiple assessments during an episode of care, such as patients who are pregnant or postpartum. We noted that in order to bill for the add-on code, the services would need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record. Based on our understanding of the typical resources costs involved in furnishing periodic assessments, we priced HCPCS code G2077 based on a crosswalk to a level 4 office/outpatient E/M visit. Consistent with our understanding of the expected acuity of patients with OUD receiving services at OTPs, including the likelihood of the patient having multiple co-morbidities and presenting with problems that are of moderate to high severity and requiring medical decision making of moderate complexity, as well as the associated payment rate assigned to this code, we explained that we believe it is important for the clinician to be able to visually assess the patient as part of any periodic assessment. Therefore, for CY 2021, we proposed that in order to bill for HCPCS code G2077, a face-to-face medical exam or biopsychosocial assessment would need to have been performed. Accordingly, we proposed to amend the definition of periodic assessment in § 410.67(b)(7) to provide that the definition is limited to a face-to-face encounter.

Additionally, we noted that in the May 8th COVID–19 IFC, CMS revised § 410.67(b)(7) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video communication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. We explained our belief that allowing periodic assessments to be furnished via two-way interactive audio-video communication technology beyond the conclusion of the PHE for COVID–19 would help to expand access to care for patients who may have a difficult time getting to the OTP in person. Therefore, in the proposed rule, we proposed to revise § 410.67(b)(7) to allow periodic assessments to be furnished via two-way interactive audio-video communication technology, provided all other applicable requirements are met. We noted that we are currently permitting the use of audio-only telephone calls to furnish these services during the PHE for COVID–19, because we believe it is important to maintain access to these services while the public is following infection control guidelines to stay at home and practice social distancing, and not all beneficiaries receiving OUD treatment services from OTPs may have access to interactive audio-video communication technology. However, we did not believe this flexibility would be needed in order to ensure access after the PHE for COVID–19 ends. Therefore, we did not propose to extend the flexibility to use audio-only telephone services to furnish periodic assessments once the PHE for COVID–19 has ended.

We noted that we would consider payment for any periodic assessment-related services furnished via audio-only telephone calls to be included in the bundled payment for a weekly episode of care, but that audio-only telephone services would not qualify for billing HCPCS code G2077 after the end of the PHE for COVID–19. We sought input from the public on whether we should consider continuing to make add-on payments for audio-only periodic assessments furnished by OTPs after the conclusion of the PHE for COVID–19, and if so, whether the payment rate for audio-only services should reflect any differences in resource costs.

We received public comments on the proposals related to periodic assessments. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to allow OTPs to utilize two-way interactive audio-video communication to satisfy the proposed requirement that periodic assessments include a face-to-face encounter. Several commenters requested that CMS allow audio only communication to continue to be used for periodic assessments beyond the PHE for beneficiaries who do not have video capabilities, noting that many individuals who receive treatment at OTPs do not have access to devices with audio-video capability and beneficiaries in rural areas may not have broadband internet access.

Response: While we believe it is important to allow the flexibility to furnish periodic assessments via audio-only telephone calls during the PHE for COVID–19, we continue to have concerns about continuing this flexibility after the end of the PHE. For example, we are concerned that the effectiveness and/or quality of the care furnished during these interactions may be lower when practitioners cannot observe visual cues while furnishing these assessments. Therefore, after consideration of the comments, we are finalizing our proposal that in order to bill for HCPCS code G2077, a face-to-face medical exam or biopsychosocial assessment would need to have been performed. Additionally, we are finalizing our proposal to revise § 410.67(b)(7) to provide that periodic assessments must be furnished during a face-to-face encounter, but may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met. We plan to analyze differences in utilization in the claims data during and after the PHE for COVID–19, and are interested in feedback related to differences in frequency, effectiveness, and quality of care furnished by OTPs when services are furnished via audio-only communication in order to help assess whether we should consider making any changes to our current policies regarding the use of communication technology in future rulemaking.

c. Date of Service

In the CY 2020 PFS final rule (84 FR 62641), we defined an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b). We have received inquiries related to the date of service used on claims for the weekly bundles and add-on codes, particularly related to an approach that many providers informed us they use, which is to establish a ''standard billing cycle'' in which episodes of care for all patients at that OTP begin on the same day of the week. We do not believe that the definition of an episode of care that was finalized for CY 2020 precludes the use of a ''standard billing cycle.'' Therefore, OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care. In this case, the date of service would be the first day of the OTP's billing cycle. If a beneficiary starts treatment at the OTP on a day that is in the middle of the OTP's standard weekly billing cycle, the OTP may still bill the applicable code for that episode of care provided that the threshold to bill for the code has been met. Alternatively, OTPs may choose to adopt weekly billing cycles that vary across patients. Under this approach, the initial date of service will depend upon the day of the week when the patient was first admitted to the program or when Medicare billing began. Therefore, under this approach of adopting weekly billing cycles that vary across patients, when a patient is beginning treatment or re-starting treatment after a break in treatment, the date of service would reflect the first day the patient was seen and the date of service for subsequent consecutive episodes of care would be the first day after the previous 7-day period ends. For the codes describing add-on services (HCPCS codes G2076–G2080), the date of service should reflect the date that service was furnished; however, if the OTP has chosen to apply a standard weekly billing cycle, the date of service for codes describing add-on services may be the same as the first day in the weekly billing cycle.

In the CY 2021 PFS proposed rule (50208), we noted that this approach is consistent with earlier guidance that was issued in the OTP Billing and Payment Fact sheet that is posted on the CMS OTP web page (*https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf*).

We received public comments on the discussion of the date of service used on claims in the proposed rule. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the flexibility to use either a ''standard billing cycle'' or a weekly billing cycle that varies across patients.

Response: We intend to continue to offer this flexibility to OTPs. Additionally, we note that the current policies regarding the date of services for add-on codes will apply to the new add-on codes we are adopting in this final rule for nasal naloxone and injectable naloxone.

d. Coding

In the CY 2021 PFS proposed rule (85 FR 50208), we explained that we recognize the importance of allowing OTPs to become accustomed to billing Medicare using the coding that was established in the CY 2020 PFS final rule; however, we remain interested in refining the code set through future rulemaking, including stratifying the coding and associated payment amounts to account for significant differences in resource costs among patients, especially in relation to amounts of expected counseling. In the CY 2020 PFS final rule (84 FR 62645), we finalized an add-on code to describe an adjustment to the bundled payment when additional counseling or therapy services are furnished, HCPCS code G2080. This add-on code may be billed when counseling or therapy services are furnished that substantially exceed the amount specified in the patient's individualized treatment plan. We stated that we have received feedback from stakeholders noting a range of OTP attendance patterns that represent a continuum of care and service intensity, noting significant differences in services received during the induction phase versus the maintenance phase. We also understand that patients' needs for service may fluctuate over time, depending on a variety of factors and circumstances. We sought comments on how we might better account for differences in resource costs among patients over the course of treatment. We noted that we would consider the comments received in developing any proposed refinements to our coding policies in future rulemaking.

We received public comments on the discussion of billing and payment policies in the proposed rule. The

following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for CMS' retaining the coding framework that was established in the CY 2020 rulemaking. A few commenters stated that CMS should maintain the current bundle structure because it has proven to be successful and viable during the first year of the new Medicare Part B benefit for OUD treatment services furnished by OTPs, and therefore there is no need to overly tinker with a functioning reimbursement structure. Another commenter stated that the current bundled payment methodology, with the ability to bill for additional counseling via add-on codes has worked remarkably well due to its simplicity. They stated that the current bundled payments reflect the costs associated with treating a patient with average needs and that while some patients require greater services and some require less, it usually balances out from a reimbursement-to-costs standpoint. They also stated that they have found that Medicare beneficiaries generally are a more health care service intensive population than non-Medicare patients, and therefore many OTPs are working to increase counseling resources to meet the unique needs of the Medicare population. They also stated that changing the current bundled payment methodology would undermine the progress OTPs have made in this area and therefore recommended that CMS maintain the current bundled payment structure.

Response: We are pleased to hear that the coding and payment policies that we established in CY 2020 PFS final rule have been effective and well received. We plan to retain the current coding structure for 2021, and will continue to consider any refinements to that structure for future rulemaking.

5. Annual Updates

In the CY 2020 PFS final rule (84 FR 62667 through 62669), we finalized a policy under which the payment for the drug component of episodes of care will be determined using the most recent data available at the time of ratesetting for the applicable calendar year. The payment for the non-drug component of the bundled payment for OUD treatment services will be updated annually based upon the Medicare Economic Index. The current payment rates, as finalized in the CY 2020 PFS final rule, both with and without locality adjustments, can be found on the CMS OTP web page under Billing and Payment at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program/billing-payment.* The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2021, is available in the file called CY 2021 PFS final rule OTP Payment Rates on the CMS website under downloads for the CY 2021 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

Comment: Commenters stated that using the Medicare Economic Index (MEI), which focuses more narrowly on physician practices, to update the payment rates for the non-drug component of the bundled payments does not ensure that Medicare payment rates for OTPs keep pace with growing practice costs. The commenters stated that OTPs' cost structures are more similar to HOPDs than they are to physician offices, in that they employ interdisciplinary teams, including medical directors, doctors, counselors, nurses, pharmacists, laboratory technicians, social workers, and case managers, to provide care to patients. They also noted that like hospitals, OTPs serve patients 7 days per week and go through extensive accreditation and certification process and are subject to thorough inspections by deferral regulators. OTPs are also required to employ diversion control systems to ensure treatment medication is being used properly, while physicians in the office setting who prescribe buprenorphine are not subject to those requirements. Commenters stated that given these similarities between OTPs and HOPDs, the IPPS market basket update would be a more accurate measure of annual price growth in the OTP setting for the non-drug component of the OTP bundled payment rates, noting that TRICARE increases its payments to OTPs by the IPPS update factor annually.

Response: We did not propose any changes for CY 2021 to the annual update process that was established in the CY 2020 PFS final rule (84 FR 62667), however, we will consider this feedback for future rulemaking.

J. Technical Correction to the Definition of Public Health Emergency

In the March 31st COVID–19 IFC (85 FR 19285), we amended 42 CFR part 400 by adding the definition of ''Public Health Emergency.'' We made an inadvertent typographical error in the regulations at § 400.200 by referring to the authority for the Public Health Emergency (PHE) as the ''Public Health Security Act'' rather than the ''Public Health *Service* Act.'' We are correcting this error in this final rule and amending § 400.200 by revising the definition. Public Health Emergency (PHE) now means the Public Health Emergency determined to exist nationwide as of January 27, 2020, by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals. This revised definition has an applicability date of March 1, 2020, which is the same applicability date as the March 31st COVID–19 IFC.

III. Summary of the Proposals for Other Part B Provisions, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

A. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions, and Comment Solicitation on Payment for Specimen Collection for COVID–19 Clinical Diagnostic Laboratory Tests

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions, under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) The amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a multi-factor productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In the June 23, 2016 **Federal Register** (81 FR 41036), we published a final rule entitled Medicare Clinical Diagnostic Laboratory Tests

Payment System (CLFS final rule), that implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016 through June 30, 2016. The first data reporting period occurred from January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of Civil Monetary Penalties (CMPs) for failure to report applicable information with respect to the initial data reporting period. This announcement is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850; 83 FR 35855 through 35862). First, we excluded Medicare Advantage (MA) plan payments under Part C from the denominator of the Medicare revenues threshold calculation, in an effort to broaden the types of laboratories qualifying as an applicable laboratory. Specifically, excluding MA plan payments could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory (if they also meet the low expenditure threshold) and report data to CMS during the data reporting period. Because MA plan payments are now excluded from the total Medicare revenues calculation, the denominator amount (total Medicare revenues) would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. This is because the laboratory's PFS and CLFS revenues are being compared to a lower total Medicare payment amount (than what they would have been compared to if MA plan payments remained in the denominator). Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. Under section 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019 through June 30, 2019, and the next data reporting period was scheduled to take place from January 1, 2020 through March 31, 2020, with the next update to the Medicare payment rates for these tests based on that reported applicable information scheduled to take effect as of January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays; or:
- *Criterion (B):* The test is cleared or approved by the FDA.

Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.*

3. Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 105(a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, enacted on December 20, 2019), and section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, enacted on March 27, 2020), made revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs under section 1834A of the Act. Additionally, the CARES Act made

revisions to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 105(a)(1) of the FCAA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2021 through March 31, 2021; the 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applies to the data reporting period of January 1, 2021 through March 30, 2021 would be the period of January 1, 2019 through June 30, 2019, which is the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS (81 FR 41036;§ 414.507(d)).

Subsequently, section 3718 of the CARES Act further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022 through March 31, 2022. As amended by the CARES Act, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that-(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2021; (ii) reporting is required during the period beginning January 1, 2022, and ending March 31, 2022; and (iii) reporting is required every 3 years after the period described in clause (ii).

The CARES Act did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2022 through March 31, 2022) will be based on the data collection period of January 1, 2019 through June 30, 2019. In § 414.502, the current definition of data collection period is defined as the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period. Additionally, in § 414.502 the data reporting period is defined as the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. Unless we revised our current definitions of data collection period and data reporting period, the definitions would have been incorrect with regard to the data collection period that applies to the next data reporting period. Therefore, we proposed to revise the definitions of data collection period and data reporting period in § 414.502 to reflect that the data collection period will be January 1, 2019 through June 30, 2019 for the data reporting period of January 1, 2022 through March 31, 2022.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2022 through 2024, instead of CYs 2021 through 2023.

4. Conforming Regulatory Changes

In accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed to make conforming changes to the data reporting and payment requirements at part 414, subpart G. Specifically, we proposed to revise § 414.502 to update the definitions of both the data collection period and data reporting period, specifying that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019. We also proposed to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. In addition, we proposed conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we proposed to revise § 414.507(d) to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We received public comments on the revised data reporting requirements and phase-in of payment reductions for the CLFS. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the proposed conforming regulatory changes to the data reporting and payment requirements.

Response: We appreciate the commenters' support for these changes that reflect the recent statutory revisions required by section 105(a) of the FCAA and section 3718 of the CARES Act.

Comment: One commenter suggested that CMS delay implementation of the phase-in of payment reductions under the CLFS.

Response: We note that the phase-in of payment reductions to the CLFS payment amounts is statutory; therefore, we are unable to delay implementation. Additionally, we note that there will be a 0.0% payment reduction for CY 2021 and, for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

In consideration of these public comments and in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we are finalizing the proposed conforming changes to the data reporting and payment requirements at part 414, subpart G.

5. Response to the Comment Solicitation on Payment for Specimen Collection for COVID–19 Clinical Diagnostic Laboratory Tests

In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (March 31st COVID–19 IFC), which displayed and became effective on March 31, 2020 and

appeared in the April 6, 2020 **Federal Register** (85 FR 19230), we established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients (85 FR 19256 through 19258). This policy provides independent laboratories with additional resources to provide COVID–19 testing and helps with efforts to limit patients' exposure to the general population and alleviate patients' unease with leaving the home. To identify specimen collection for COVID–19 testing specifically, we established two new level II HCPCS codes: Code G2023 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) (Coronavirus disease [COVID–19]), any specimen source*); and code G2024 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–Cov–2) (Coronavirus disease [COVID19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source*), for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the PHE for COVID–19.

We indicated in the March 31st COVID–19 IFC that this specimen collection fee policy was established for the duration of the PHE for COVID–19 (85 FR 19256). In the CY 2021 PFS proposed rule, we requested comments on whether we should delete HCPCS codes G2023 and G2024 once the PHE for COVID–19 ends (85 FR 50211). We noted that comments received may inform a future proposal. Specifically, we sought public input on why these codes, and their corresponding payment amounts, which are higher than the nominal specimen collection fees for other conditions, would be necessary or useful outside of the context of the PHE for COVID–19. We stated that we were particularly interested in why separate, increased payment for specimen collection specifically for COVID–19 tests, in contrast to other tests, may be needed following the end of the PHE.

We received public comments on the specimen collection fees for COVID–19 clinical diagnostic laboratory tests. The following is a summary of the comments we received and our response.

Comment: Several commenters expressed support for permanently extending payment for specimen collection for COVID–19 tests after the PHE, as commenters expect the COVID–19 virus to be present into CY 2021, thus making it appropriate for CMS to continue to pay for specimen collection. Commenters recommended that CMS expand and permanently authorize the specimen collection fees under HCPCS codes G2023 and G2024 to apply to all CDLTs to compensate for the supplies, equipment, and sterilization protocols required for safe and uncontaminated specimen collection and handling in the presence of COVID–19. Commenters noted that COVID–19 will continue to spread and may become an ongoing and/or seasonal infectious disease event, and because of this possibility, they expect that the heightened safety precautions, the need for personal protective equipment, and the requirement for special training for specimen collection will persist beyond the immediate PHE.

Commenters also recommended that CMS confirm that HCPCS code G2023 applies to any site where clinical laboratory personnel collect specimens, and not solely to homebound and nonhospital inpatients. Some commenters requested that CMS confirm that when a laboratory receives a health care professional's order for COVID–19 test specimen collection in a beneficiary's home, the laboratory may consider this order to be a determination by the health care professional that the beneficiary is homebound, and therefore, the laboratory is eligible for the increased specimen collection fee represented by HCPCS code G2023.

Response: We appreciate the comments regarding the nominal specimen collection fees and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing. We plan to take this feedback into consideration for possible future rulemaking or guidance.

B. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

1. Modifications to OTP Enrollment Process

a. Background

Under 42 CFR 424.510, a provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the Form CMS–855 (OMB Control No. 0938–0685) application to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System), captures information about the provider or supplier that CMS or its MACs reviews and verifies to determine whether the provider or supplier meets all Medicare requirements. (The specific Form CMS–855 application (of which there are several variations) to be completed will depend upon the type of provider or supplier submitting said application.) This process of enrollment helps ensure that: (1) All prospective providers and suppliers are carefully screened and reviewed; and (2) unqualified providers and suppliers are kept out of the Medicare program, which helps protect the Trust Funds and Medicare beneficiaries. Indeed, without this process, billions of taxpayer dollars might be paid to fraudulent or otherwise non-compliant parties.

b. Completion of Form CMS–855

Existing § 424.67 outlines a number of enrollment requirements for OTPs. One requirement, addressed in § 424.67(b)(1), is that OTPs must complete the Form CMS–855B application (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB #: 0938–0685) to enroll in Medicare. The reference to the Form CMS–855B in § 424.67(b)(1) was predicated in part on the assumption that OTPs would generally submit the CMS–1500 claim form (Health Insurance Claim Form; OMB Control No.: 0938–1197) to receive payment for their services. However, as mentioned previously in section II.I.4. of the CY 2021 PFS proposed rule (85 FR 50074), we have received requests to allow OTPs to bill for services on an institutional claim form (specifically, the 837I). To do so, these OTPs would have to enroll in Medicare via the Form CMS–855A (Medicare Enrollment Application for Institutional Providers (OMB #: 0938–0685)). To account for circumstances where an OTP wishes to pursue Form CMS–855A enrollment for the reason stated above, we proposed the following revisions to § 424.67:

- Current § 424.67(b)(1) states that a newly enrolling OTP must fully complete and submit the Form CMS–855B application (or its successor application). We proposed to revise this paragraph to state that the newly enrolling OTP must fully complete and submit, as applicable, the Form CMS–855A or Form CMS–855B application (or their successor applications).
- Existing § 424.67(b)(1)(ii) requires the OTP to certify compliance with the requirements and standards described in paragraphs § 424.67(b) and (d) via the Form CMS–855B and/or the applicable

supplement or attachment thereto. We proposed to revise this paragraph such that the OTP must certify compliance with the above-referenced requirements and standards via the Form CMS–855A or Form CMS–855B (as applicable) and/or the applicable supplement or attachment thereto.

• Existing § 424.67(b)(5) requires the OTP to report on the Form CMS–855B and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. We proposed to change this to state that the OTP must report on the Form CMS–855A or Form CMS–855B (as applicable) and/or any applicable supplement all OTP staff who meet this definition.

We believed these revisions would accomplish two objectives. First, they would permit OTPs to submit a Form CMS–855A in lieu of a Form CMS–855B based on their preferred method of billing. Second, they would confirm that the requirements of § 424.67 apply to all OTPs regardless of whether they complete the Form CMS–855A or the Form CMS–855B.

c. Screening Activities Associated With Risk Designation

Section 424.518 outlines provider enrollment screening categories and requirements based on our assessment of the degree of risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type presents, the greater the degree of scrutiny with which we will screen and review enrollment applications submitted by providers or suppliers within that category. There are three levels of screening addressed in § 424.518: Limited; moderate; and high. Irrespective of which level a provider or supplier type falls within, the MAC performs certain minimum screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location. These include:

• Verification that the provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.

• State license verifications.

• Database reviews on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Moreover, for those in the high categorical risk level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are intended to correspond to the heightened risk involved with such provider or supplier types.

For newly enrolling OTPs, those that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018 fall within the moderate level of categorical screening. OTPs that have not been so certified since the aforementioned date are subject to the high screening level. As discussed in the CY 2021 PFS proposed rule (85 FR 50074), we recognize that certain providers and suppliers have already enrolled as OTPs via the Form CMS–855B—and, accordingly, undergone a site visit and, if applicable, fingerprinting—but would seek to newly enroll via the Form CMS–855A should our proposals be finalized. (Said enrollment would be considered ''new'' for purposes of enrollment because the OTP would be enrolling via a different variation of the Form CMS–855.) While not seeking to minimize the importance of the enhanced screening activities associated with the moderate and high categorical levels, we do not wish to unduly burden currently enrolled OTPs that would pursue Form CMS–855A enrollment as an OTP. More specifically, we noted that we did not believe such OTPs should have to undergo another site visit and, if applicable, fingerprinting when they previously did so as an OTP via their original Form CMS–855B enrollment. This, in our view, would constitute an unnecessary expenditure of CMS, MAC, and OTP resources. We add that the same would hold true if, in the future, an OTP that is enrolled via the Form CMS–855A under revised § 424.67(b) decides to change to a Form CMS–855B enrollment. In both cases, we believe a duplication of effort should be avoided to the extent consistent with safeguarding the integrity of the Medicare program.

Existing § 424.67(b)(3) states that an enrolling OTP must successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c) (which outline the screening requirements for newly enrolling parties in, respectively, the moderate and high categorical levels). Given the foregoing discussion, we proposed several changes to § 424.67(b)(3). First, we proposed to redesignate existing § 424.67(b)(3) as new § 424.67(b)(3)(i), though with an exception to its requirements. Second, and to address this exception, we proposed to add paragraph (b)(3)(ii) to state that currently enrolled OTPs that are changing their OTP enrollment from a Form CMS–855B to a Form CMS–855A, or vice versa, must successfully complete the limited level of categorical screening under § 424.518(a) if the OTP has already completed, as applicable, the moderate or high level of categorical screening under § 424.518(b) or (c), respectively. Third, we proposed to redesignate existing § 424.518(a)(1)(xii) through (xvii) as § 424.518(a)(1)(xiii) through (xviii). Fourth, proposed new § 424.518(a)(1)(xii) would add OTPs that fall within the purview of new paragraph (b)(3)(ii) to the provider and supplier types subject to limited risk categorical screening.

d. Additional OTP Enrollment Clarifications Regarding the Form CMS–855A

We proposed three additional clarifications related to our previously mentioned OTP enrollment provisions. To incorporate these into § 424.67, we proposed to redesignate existing paragraphs (c), (d), (e), and (f) as paragraphs (d), (e), (f), and (g), respectively. The three clarifications would be included in new paragraph (c).

With the redesignation of existing paragraph (d) as paragraph (e), we also proposed to change the reference to:

• Paragraph (d) in existing paragraph (b)(1)(ii) to paragraph (e).

• Paragraph (d)(1) in existing paragraph (d)(2)(i) to paragraph (e)(1) in redesignated paragraph (e)(2)(i).

(1) Single Enrollment

We proposed in new § 424.67(c)(1) that an OTP may only be enrolled as such via the Form CMS–855A or the Form CMS–855B but not both. The OTP, in other words, must opt for either Form CMS–855A enrollment or Form CMS–855B enrollment. This is to help ensure that the OTP does not bill twice for the same service via separate claim vehicles (specifically, the CMS–1500 and the 837I).

(2) Effective Date of Billing

Section 424.520(d) outlines the effective date of billing privileges for newly enrolling OTPs (and certain other provider and supplier types). This date is the later of: (1) The date of the OTP's filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the OTP first began furnishing services at a new practice location. In a similar vein, § 424.521(a) states that OTPs (and certain other provider and supplier types) may retrospectively bill for services when the OTP has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to—

- 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

In light of proposed § 424.67(c)(1) (and as further explained in the collection of information section of this proposed rule), we anticipate that a number of OTPs would end their existing enrollment and apply as a new OTP via, as applicable, the Form CMS–855A or Form CMS–855B. Given this, we believe it is important to clarify for stakeholders the new enrollment's effective date of billing. Accordingly, at § 424.67, we proposed in new paragraph (c)(2) that if a Form CMS–855B-enrolled OTP changes to a Form CMS–855A enrollment, or vice versa, the effective date of billing that was established for the OTP's prior enrollment under §§ 424.520(d) and 424.521(a) would be applied to the OTP's new enrollment. This would allow OTPs that have been unable to bill for furnished services via their preferred claim form (and have consequently chosen to delay the submission of these claims for services) to do so retroactive to the effective billing date of its prior enrollment. To illustrate, suppose an OTP initially enrolled via the Form CMS–855B in 2020. The effective date of billing was April 1, 2020. Wishing to submit an 837I claim form for the services it has provided since April 1, 2020, the OTP elects to end its Form CMS–855B enrollment and enroll via the Form CMS–855A pursuant to revised § 424.67. It successfully does the latter in March 2021. Under § 424.67(c)(2), the billing effective date of the Form CMS–855A enrollment would be retroactive to April 1, 2020. However, we noted in the proposed rule that the time limits for filing claims found in § 424.44 would continue to apply. Specifically, all Medicare Part A and Part B claims must be filed within 1 calendar year after the date of service unless one of a very limited number of exceptions applies. Switching from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, is not grounds for an exception.

We recognized that not every OTP that seeks to change its enrollment will have chosen to withhold submission of all of its claims under its prior enrollment. (Using our example in the previous paragraph, the OTP may have submitted some claims via the CMS–1500 while planning to eventually submit the remaining ones via the 837I.) Irrespective of this, CMS has long had operational safeguards in place to prevent double-billing for the same service. Said protections would be used in the scenario described in proposed § 424.67(c)(2) so that claims submitted under the prior enrollment could not be resubmitted under the new one.

(3) Application Fee

As stated in § 424.514, prospective and revalidating institutional providers that are submitting a Medicare enrollment application generally must pay the applicable application fee in accordance with § 424.514. (For CY 2020, the fee amount is $595.) The term ''institutional provider'' is defined in § 424.502 as any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and NPP organizations, which are exempt from the fee requirement if they are enrolling as a physician or NPP organization), Form CMS–855S, Form CMS–20134, or an associated internet-based PECOS enrollment application.

As stated previously, OTPs currently complete the Form CMS–855B to enroll in Medicare. They are considered ''institutional providers'' (as defined in § 424.502) and must pay an application fee, a requirement addressed in existing § 424.67(b)(2). Since the existing OTPs referenced in new paragraph (c)(2) would be enrolling as new providers via the Form CMS–855A or Form CMS–855B (as applicable), we stated our belief in the proposed rule that they would fall within the scope of both (1) the aforementioned definition of ''institutional provider'' and (2) § 424.514(a)(1); as described therein, § 424.514(a)(1) applies to prospective institutional providers that are submitting an initial application. To clarify this issue for the OTP community, we proposed to add language to § 424.67(b)(2) stating that compliance with the application fee requirements in § 424.514 would also apply to those OTPs enrolling under the circumstances described in § 424.67(c)(2).

We emphasized that the flexibilities described in this section III.B. are complementary to those in section II.I. (''Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs))'' regarding OTP billing via the 837I. Our OTP enrollment revisions are intended to facilitate greater flexibility for OTPs.

We received the following public comment on our OTP provider enrollment proposals:

Comment: Several commenters supported our proposal to permit an OTP to enroll via the Form CMS–855B or the Form CMS–855A. One commenter also questioned whether this applies to a Medicare OTP Part B provider sharing the same clinical space as a Medicare Part A provider.

Response: We appreciate the commenters' support. However, we emphasize that an OTP may only enroll as such via the Form-855B or the Form-855A, not both. In the situation the OTP appears to describe, the OTP operating in the clinical space in question would have to elect which of the two available enrollment mechanisms to pursue.

Based on the comments received, we are finalizing our provisions pertaining to OTP enrollment as proposed.

C. Payment for Principal Care Management (PCM) Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PA), certified nurse midwives (CNMs), clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management (TCM) service can also be an RHC or FQHC

visit. In addition, a Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT program may also count as an FQHC visit. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per visit payment.

RHCs are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B Medicare Administrative Contractor (MAC) calculates the AIR for the year for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for certain provider-based RHCs that have an exception to the payment limit.

FQHCs were paid under the same AIR methodology until October 1, 2014 when, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to an FQHC PPS system in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF).

b. Care Management Services in RHCs and FQHCs

In the CY 2018 PFS final rule with comment period (82 FR53180), we finalized revisions to the payment methodology for Chronic Care Management (CCM) services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2019. Specifically, we revised § 405.2464(c) to permit RHCs and FQHCs to bill for care management services (HCPCS codes G0511 and G0512).

HCPCS code, G0511, is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month.

The payment amount for HCPCS code G0511 is set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are CPT 99490 (*20 minutes or more of CCM services*), CPT 99487 (*60 minutes or more of complex CCM services*), and CPT 99484 (*20 minutes or more of BHI services*).

In the CY 2019 PFS final rule with comment period (83 FR 59687), we added CPT code 99491 (*30 minutes or more of CCM furnished by a physician or other qualified health care professional*) as a general care management service and included it in the calculation of HCPCS code G0511. Beginning January 1, 2019, the payment for HCPCS code G0511 is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 and is updated annually based on the PFS amounts. Additional information on CCM requirements is available on the CMS Care Management web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html*, and on the CMS RHC and FQHC web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html*.

2. Requirements for PCM Services in RHCs and FQHCs

In the CY 2020 PFS final rule with comment (84 FR 62692), we established a separate payment for PCM services. PCM services include comprehensive care management services for a single high-risk disease or complex condition, typically expected to last at least 3 months and may have led to a recent hospitalization, and/or placed the patient at significant risk of death. Beginning January 1, 2020, practitioners billing under the PFS can bill for PCM services using HCPCS codes G2064 or G2065.

HCPCS code G2064 is for at least 30 minutes of PCM services furnished by physicians or NPPs during a calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan; the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization; the condition requires development or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen; and/or the management of the condition is unusually complex due to comorbidities.

HCPCS code G2065 is for at least 30 minutes of PCM services furnished by clinical staff under the direct supervision of a physician or NPP with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan; the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization; the condition requires development or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen; and/or the management of the condition is unusually complex due to comorbidities.

In the CY 2021 PFS proposed rule (85 FR 50214), we stated that a national stakeholder organization representing rural health clinics requested that RHCs be allowed to furnish and bill for PCM services. We agreed that there can be significant resources involved in care management for a single high-risk disease or complex chronic condition, and that the requirements for the new PCM codes are similar to the requirements for the care management services described by HCPCS code G0511. We explained that these are services that do not currently meet the requirements for an RHC or FQHC billable visit, and they provide an array of care management services that are not generally included in the RHC AIR or the FQHC PPS. Therefore, we proposed to add HCPCS codes G2064 and G2065 to G0511 as a comprehensive care management service for RHCs and FQHCs starting January 1, 2021. The payment rate for HCPCS G0511 is set at the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and we proposed that these 2 new codes be added to the calculation of the G0511 payment rate.

3. Other Options Considered

In the CY 2021 PFS proposed rule (85 FR 50214), we stated that we also considered creating a separate G code for PCM services. We did not propose this approach because PCM and CCM are similar services and grouping them together is consistent with an integrated approach to care with reduced reporting

requirements. As we stated in the CY 2018 PFS final rule, if a new care management code is proposed and subsequently finalized for practitioners billing under the PFS, we would review the new code to determine if it should be included in the calculation of the RHC and FQHC General Care Management Code. The determination of whether a new care management code should be added to the codes used to determine the payment rate is based on the applicability of the service in RHCs and FQHCs, and may result in either an increase or decrease in the payment amount for HCPCS code G0511.

4. Implementation

In the CY 2021 PFS proposed rule (85 FR 50214), we explained that if this proposal is finalized as proposed, RHCs and FQHCs that furnish PCM services would also be able to bill the services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2021. The payment rate for HCPCS code G0511 would continue to be the average of the national non-facility PFS payment rates for the RHC/FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491). HCPCS G2064 and G2065 would be added to G0511 to calculate a new average for the national non-facility PFS payment rate. The payment rate for HCPCS code G0511 would be updated annually based on the PFS amounts for these codes.

We received approximately 27 public comments on the proposed requirements for PCM services in RHCs and FQHCs from a mix of stakeholders, including individuals, associations, advocate groups, and provider groups. The following is a summary of the comments we received and our responses.

Comment: All commenters supported the proposal to add the PCM HCPCS codes to the general care management HCPCS code (G0511) for care management services furnished in RHCs and FQHCs. One commenter recommended we create two new G codes for PCM services furnished in RHCs and FQHCs. A few commenters suggested that CMS waive the coinsurance for PCM services.

Response: Per the comment that recommended that we create two new G codes, we considered creating new G codes for PCM services as we stated in the CY 2021 PFS proposed rule (85 FR 50214); however, we explained that since the requirements for PCM services are similar to the requirements for care management services furnished in an RHC and FQHC, grouping them together is consistent with an integrated approach to care with reduced reporting requirements.

Regarding the comment suggesting that CMS waive the coinsurance for PCM services, we remind commenters that we have no authority to waive coinsurance for care management services. Coinsurance for care management services is 20 percent of lesser of submitted charges or the payment rate for general care management HCPCS code.

Comment: We received several public comments that were out-of-scope for this rule. Commenters requested that CMS expand certain flexibilities provided during the PHE for COVID–19, including the addition of services to the Medicare Telehealth Services List. In addition, several commenters requested that CMS create a separate G code for remote physiologic monitoring (RPM) services and add RPM treatment management services (RPMTMS) to the general care management services.

Response: We appreciate the feedback from commenters, and will continue to monitor Medicare telehealth services during the PHE for COVID–19. RHCs are paid an AIR when a medically-necessary, face-to-face visit is furnished by an RHC practitioner. FQHCs are paid the lesser of their charges or the FQHC PPS rate when a medically-necessary, face-to-face visit is furnished by an FQHC practitioner. Both the RHC AIR and the FQHC PPS rate include all services and supplies furnished incident to the visit. Services such as RPM are not separately billable because they are already included in the RHC AIR or FQHC PPS payment. We may consider analyzing the RPMTMS services and how they would impact the payment for general care management services in future rulemaking; however, we note that we did not specifically make any proposals associated with these subjects in the CY 2021 PFS proposed rule.

In consideration of these public comments, we are finalizing the proposal to add the PCM HCPCS codes, G2064 and G2065, to the general care management code, G0511, as a comprehensive care management service for RHCs and FQHCs, starting January 1, 2021 as proposed. We are also finalizing that when RHCs and FQHCs furnish PCM services, they will also be able to bill the services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2021. The payment rate for HCPCS code G0511 will be the average of the national non-facility PFS payment rates for the RHC/FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491) with the addition of HCPCS G2064 and G2065. That is, the PCM services will be added to G0511 to calculate a new average for the national non-facility PFS payment rate. The payment rate for HCPCS code G0511 will be updated annually based on the PFS amounts for these codes.

D. Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Rebasing and Revising of the FQHC Market Basket

1. Background

Section 10501(i)(3)(A) of the Affordable Care Act added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC final rule published in the May 2, 2014 **Federal Register** (79 FR 25436), we implemented a methodology and payment rates for the FQHC PPS. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods, and as of January 1, 2016, all FQHCs have been paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the Medicare Economic Index (MEI). Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI is based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS sustainable growth rate (SGR) formula to determine the CF for physician service payments. (See the CY 2014 PFS final rule (78 FR 74264) for a complete discussion of the 2006-based MEI.) Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based market basket reflecting the operating and capital cost structures for freestanding FQHC facilities (hereafter referred to as the FQHC market basket). A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403).

In the CY 2021 PFS proposed rule (85 FR 50214 through 50223), we proposed

to rebase and revise the 2013-based FQHC market basket to reflect a 2017 base year. The proposed 2017-based FQHC market basket is primarily based on Medicare cost report data for FQHCs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and prior to September 31, 2017. We proposed to use data from cost reports beginning in FY 2017 because these data are the latest available complete data for purposes of calculating cost weights for the market basket at the time of rulemaking.

In the following discussion, we provide an overview of the proposed FQHC market basket, describe the proposed methodologies for developing the 2017-based FQHC market basket, and provide information on the proposed price proxies. We then describe any comments received, responses to these comments, and our final decision for this final rule.

2. Overview of the 2017-Based FQHC Market Basket

Similar to the 2013-based FQHC market basket, the proposed 2017-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured. The index itself is constructed using three steps. First, a base period is selected (we proposed to use 2017 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe. As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a FQHC hiring more nurse practitioners to accommodate the needs of patients would increase the volume of goods and services purchased by the FQHC, but would not be factored into the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that FQHCs purchase (FQHC inputs) to furnish inpatient care.

3. Development of the 2017-Based FQHC Market Basket Cost Categories and Weights

We solicited public comments on the proposed methodology for deriving the 2017-based FQHC market basket.

a. Use of Medicare Cost Report Data

We proposed a 2017-based FQHC market basket that consists of eleven major cost categories and a residual derived from the 2017 Medicare cost reports (CMS Form 224–14, OMB Control Number 0938–1298) for FQHCs, hereafter referred to as the 2014 Medicare Cost Report form. The eleven cost categories are FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Medical Supplies, Pharmaceuticals, Fixed Capital and Moveable Capital. The residual category reflects all remaining costs not captured in the 11 cost categories such as non-medical supplies and utilities for example. We noted that for the 2013-based FQHC market basket, we estimated six cost categories from the Medicare cost reports (CMS Form 222–92, OMB Control Number 0938–0107), hereafter referred to as the 1992 Medicare cost report form: FQHC Practitioner Compensation, Clinical Staff Compensation, Non-Health Staff Compensation, Pharmaceuticals, Fixed Capital and Moveable Capital.

The resulting 2017-based FQHC market basket cost weights reflect Medicare allowable costs. We proposed to define Medicare allowable costs for freestanding FQHC facilities as the total expenses reported on: Worksheet A, columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, column 1, lines 23 through 36; and Worksheet S3 Part II, columns 1 and 2, lines 2 through 14. We noted that we continue to exclude Professional Liability Insurance (PLI) costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act).

The following is a summary of how we proposed to derive the eleven major cost category weights. Prior to estimating any costs, we remove any providers that did not report any total gross patient revenues as reported on the FQHC cost report Worksheet F–1, line 1, column 4.

(1) FQHC Practitioner Wages and Salaries Costs

A FQHC practitioner is defined as one of the following occupations: Physicians; nurse practitioners (NPs); physician assistants (PAs); certified-nurse midwife (CNMs); clinical psychologist (CPs); and clinical social workers (CSWs). We proposed to derive FQHC Practitioner Wages and Salaries costs as the sum of direct care costs salaries as reported on Worksheet A, column 1, lines 23, 25, 26, 29, 30, and 31. These lines represent the wages and salaries costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. For the 2013-based FQHC market basket, we estimated FQHC Practitioner Total Compensation costs based on a similar methodology using cost data reported on Worksheet A of the 1992 Medicare cost report form (81 FR 80394) for specific details on the prior methodology.

(2) FQHC Practitioner Employee Benefits Costs

Effective with the implementation of the 2014 Medicare cost report form, we began collecting Employee Benefits and Contract Labor data on Worksheet S–3, part II and proposed to derive FQHC Practitioner Employee Benefits costs using data obtained from that worksheet. Approximately 66 percent of FQHCs included in the sample of FQHCs reporting Salary costs also reported data on Worksheet S–3, part II for 2017. We continue to encourage all providers to report these data on the

Medicare cost report. Therefore, we proposed to calculate FQHC Practitioner Employee Benefits costs using Worksheet S–3, part II data. Specifically, we proposed to use data from Worksheet S–3, part II, column 2, lines 2, 3, 4, 7, 8, and 9 to derive FQHC Practitioner Employee Benefits costs. These lines represent the employee benefits costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. Our analysis of the Worksheet S–3, part II data submitted by these FQHCs indicates that we had a large enough sample to enable us to produce a reasonable Employee Benefits cost weight.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate FQHC Practitioner Employee Benefits costs, and instead computed FQHC Practitioner Total Compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. Anytime direct costs can be obtained for a cost category directly from the Medicare Cost Reports we consider that to be a technical improvement to the market basket weight methodology as it allows the index to reflect the relative shares specific to the provider type. Therefore, as discussed in the CY 2021 PFS proposed rule, we noted that we believe the proposed method of separately estimating FQHC Practitioner Employee Benefits is a technical improvement over the 2013-based FQHC market basket.

(3) FQHC Practitioner Contract Labor Costs

FQHC Practitioner Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described below. Approximately 60 percent of FQHCs reported contract labor costs on Worksheet S–3, part II, which we noted that we believe is an adequate sample size to enable us to produce a reasonable FQHC Practitioner Contract Labor cost weight. Therefore, we proposed to derive the FQHC Practitioner Contract Labor costs for the proposed 2017-based FQHC market basket from data reported on Worksheet S–3, part II, column 1, lines 2, 3, 4, 7, 8, and 9. These lines represent the contract labor costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. We would also add in the costs for physician services under agreement as reported on Worksheet A, column 2, line 24 to derive the total FQHC Practitioner Contract Labor cost weight in the 2017-based FQHC market basket.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate FQHC Practitioner Contract Labor costs and instead computed FQHC Practitioner Total Compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. As noted previously, anytime direct costs can be obtained for a cost category directly from the Medicare Cost Reports we consider that to be a technical improvement to the market basket weight methodology as it allows the index to reflect the relative shares specific to the provider type. Therefore, we noted that we believe the proposed method of separately estimating FQHC Practitioner Contract Labor is a technical improvement over the 2013-based FQHC market basket.

(4) Clinical Staff Wages and Salaries Costs

Clinical Compensation includes any health-related clinical staff who does not fall under the definition of a FQHC Practitioner described in paragraph. We proposed to derive Clinical Staff Wages and Salaries costs as the sum of direct care costs salaries as reported on Worksheet A, column 1, lines 27, 28, 32, 33, 34, 35, and 36. These lines represent the wages and salaries costs for visiting registered nurses (RNs), visiting licensed practical nurses (LPNs), laboratory technicians, registered dietician/Certified DSMT/MNT educators, physical therapists (PTs), occupational therapists (OTs), and other allied health personnel.

- For the 2013-based FQHC market basket, we estimated a clinical staff total compensation cost based on a similar methodology using cost data reported on Worksheet A of Medicare Cost Report Form CMS–222–92, (see 81 FR 80394 for specific details on the prior methodology).

(5) Clinical Staff Employee Benefits Costs

Effective with the implementation of the 2014 Medicare cost report form, we began collecting employee benefits and contract labor data on Worksheet S–3, part II and proposed to derive clinical staff employee benefits costs using data obtained from that worksheet. Approximately 64 percent of FQHCs included in the sample of FQHCs reporting salary expenses also reported data on Worksheet S–3, part II for 2017. We noted that we continue to encourage all providers to report these data on the Medicare cost report. Therefore, we proposed to calculate clinical staff employee benefits costs using Worksheet S–3, part II, column 2, lines 5, 6, 10, 11, 12, 13, and 14. These lines represent the employee benefits costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel.

- For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate clinical staff employee benefits costs and instead computed clinical staff total compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. We noted that we believe the proposed method of separately estimating clinical staff employee benefits is a technical improvement over the 2013-based FQHC market basket.

(6) Clinical Staff Contract Labor Costs

We proposed to derive the clinical staff contract labor costs for the proposed 2017-based FQHC market basket from data reported on Worksheet S–3, part II, column 1, lines 5, 6, 10, 11, 12, 13, and 14 to derive clinical staff contract labor costs. These lines represent the contract labor costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate clinical staff contract labor costs and instead computed clinical staff total compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. We noted that we believe the proposed method of separately estimating FQHC clinical staff contract labor is a technical improvement over the 2013-based FQHC market basket.

(7) Non-Health Staff Compensation Costs

Non-Health Staff Compensation includes wage and salary costs for personnel in general service cost centers including: Employee Benefits department; Administrative & General; Plant Operation & Maintenance; Janitorial; Medical Records; Pharmacy; Transportation; and Other General Services. Specifically, non-health staff compensation costs are derived as the sum of compensation costs as reported on Worksheet A, column 1 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Additionally, we add a portion of employee benefit costs reported on Worksheet A, line 3, column 2 accounting for the non-health staff. We

estimate the ratio of non-health staff related wages and salaries as a percentage of total wages and salaries. We then apply the percentage of non-health staff related wages and salary costs to the total employee benefits costs (Worksheet A, line 3, column 2) for each FQHC. We noted that we believe this is a reasonable estimate of non-health staff employee benefits. We proposed to only use the costs from column 1 for most of the general service cost centers other than employee benefits since we believe that there are noncompensation costs reported in column 2 (such as maintenance and janitorial supplies). The remaining other costs for the general service categories are reflected in the remaining proposed cost categories as explained in more detail below.

(8) Pharmaceuticals Costs

We proposed to calculate pharmaceuticals costs using the non-salary costs for the pharmacy cost center reported on Worksheet A, column 2, line 9. We proposed to exclude the costs for drugs charged to patients as reported on Worksheet A, line 67 since these drugs are not included in the Medicare allowable costs for the FQHC PPS and are separately reimbursed. For the 2013-based FQHC market basket we were not able to exclude non-reimbursable drug costs (such as drugs charged to patient costs) from the pharmacy cost weight as the 1992 Medicare cost report form did not capture these costs separately. We noted that we believe our proposed methodology is a technical improvement as it is more consistent with the FQHC PPS reimbursement.

(9) Medical Supplies

We proposed to calculate medical supplies costs using the non-salary costs for the medical supplies cost center reported on Worksheet A, column 2, line 10. The medical supplies cost weight for the 2013-based FQHC market basket was derived based on the relative share of the medical supply costs in the MEI since these costs were not separately reported on the 1992 Medicare cost report form (81 FR 80395 through 80396). Since these costs are now directly reported by FQHC providers we noted that we believe that the proposed method is a technical improvement to the method used in the 2013-based FQHC market basket.

(10) Fixed Capital

We proposed that fixed capital costs be equal to costs reported on Worksheet A, line 1, column 2 of the Medicare Cost Report. A similar methodology was used for the 2013-based FQHC market basket.

(11) Moveable Capital Costs

We proposed that moveable capital costs be equal to the capital costs as reported on Worksheet A, line 2, column 2. A similar methodology was used for the 2013-based FQHC market basket.

Comment: Several commenters expressed support, as well as some concerns with the proposed use of the Medicare cost reports. Specifically, the commenters supported the proposed use of the Medicare cost report data to derive eleven major cost categories in the 2017-based FQHC market basket—an increase from 6 cost categories used in the 2013-based FQHC market basket. They stated this calculation will give a broader base to more accurately compute the increasing costs of providing FQHC services.

The commenters also agreed with the proposed lines included in the calculation of the Medicare Allowable total expenses (Worksheet A, columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, column 1, lines 23 through 36; and Worksheet S3 Part II, columns 1 and 2, lines 2 through 14). However, they disagreed with the use of columns 1 and 2 from Worksheet A to capture a health center's expenses because they reflect their internal accounting records in accordance with generally accepted accounting principles (GAAP). The commenters noted that the net expenses as listed in Worksheet A, column 7 of the Medicare cost report most accurately reflects Medicare allowable cost for a community health center as these reflect the reclassification entries which are common on the Medicare cost report, particularly for expenses related to compensation and drugs. They also noted that CMS must factor in the reclassification and adjustment entries that are recorded on health center Medicare cost reports to accurately calculate a 2017-based market basket that reflects the change in Medicare allowable costs. Furthermore, the commenters noted that the costs that are used to calculate the costs per visits in Worksheet B reflect the reclassifications and adjustments and so the 2017-based FQHC market basket should be calculated using the same cost information.

Response: Using the data from the net cost column (column 7) presents unique challenges because a detailed breakdown of the net expenses is not provided on the FQHC cost report, particularly for employee benefits, which is why we proposed to utilize the data from Worksheet A column 1 and 2 to estimate salary and all other costs. Specifically, the FQHC cost report does not have a detailed step down of the net expenses allocated to each General Service cost center like other provider cost reports such as the hospice cost report (CMS Form 1984–14). This means that for some categories, particularly Employee Benefits cost center, we must make assumptions on how the total employee benefit costs are allocated across cost centers. On the other hand, Worksheet B on the hospice cost report gives a detailed allocation of General Service cost centers' net expenses (including employee benefits) across the patient-care cost centers.

Based on the commenters' concerns, we reviewed the FQHC Medicare cost report data and found that a large percentage of providers had reclassifications and adjustments and these had an impact on the distribution of total expenses among the major cost weight categories, particularly pharmaceuticals and FQHC practitioner salaries. Therefore, based on public comments, for this final rule we are revising our methodology from the proposed rule to reflect the use of net expenses as reported on Worksheet A, column 7 rather than the proposed Worksheet A, column 1 and column 2 to derive the FQHC cost share weights. Below we provide the revised detailed methodology for the major market basket cost weights in response to public comment.

In response to public comments to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Medicare allowable costs for freestanding FQHC facilities as the total expenses reported on: Worksheet A, column 7, for lines 1 through 7, lines 9 through 12, and lines 23 through 36. These are the same cost centers that were used in the proposed market basket for which the commenters agreed was appropriate.

(1–3) FQHC Practitioner Compensation (Wages & Salaries, Benefits, and Contract Labor)

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining the FQHC Practitioner Compensation as the sum of net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 23, 25, 26, 29, 30, and 31. These lines represent the total net costs for physicians, PAs, NPs, CNMs, CPs, and CSWs—the same lines that were used for the proposed methodology for which the commenters agreed was appropriate. Using this finalized methodology, we derive a 2017-based FQHC market

basket FQHC Practitioner Compensation cost weight of 28.4 percent compared to the proposed rule with 30.0 percent.

To further divide the FQHC Practitioner Compensation costs into FQHC Practitioner Wages and Salaries, Benefits, and Contract Labor costs, we are using the shares derived for each of these costs using the proposed methodologies for each FQHC provider as described in sections III.D.3.a.1, D.3.a.2 and D.3.a.3 of this final rule. Specifically, for each line included in the FQHC Practitioner category, the FQHC Practitioner Wages and Salaries costs is equal to the FQHC Practitioner Compensation costs as described above multiplied by the FQHC Practitioner Wages and Salaries costs (described in section III.D.3.a.1 of this final rule) as a percent of FQHC Practitioner Compensation costs. This revised methodology reflects the net expenses (Worksheet A, column 7) to address the commenters' concerns while also using the Medicare cost report data to reflect the split among the types of compensation costs: Wages and salaries, employee benefits, and contract labor.

Therefore, for this final rule, in response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, the FQHC Practitioner Wages and Salaries cost weight is 19.4 percent, and accounts for 68 percent of the FQHC Practitioner Compensation cost weight. The FQHC Practitioner Employee Benefit cost weight is 4.5 percent, and accounts for 16 percent of the FQHC Practitioner Compensation cost weight. The FQHC Practitioner Contract Labor cost weight is 4.6 percent, and accounts for 16 percent of the FQHC Practitioner Compensation cost weight.

(4–6) Clinical Staff Compensation (Wages & Salaries, Benefits, and Contract Labor)

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Clinical Staff Compensation costs as the sum of net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 27, 28, 32, 33, 34, 35, and 36. These lines represent the net expenses for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel—the same lines that were used for the proposed methodology for which the commenters agreed was appropriate. Using this finalized methodology, we derive a 2017-based FQHC market basket Clinical Staff Compensation cost weight of 16.8 percent compared to the proposed rule with 16.2 percent.

To further divide the Clinical Staff Compensation costs into Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, and Clinical Staff Contract Labor costs, we are using the shares derived for each of these costs using the proposed methodologies for each FQHC provider as described in sections III.D.3.a.4, D.3.a.5 and D.3.a.6. of this final rule. Specifically, for each line included in the Clinical Staff Compensation category, the Clinical Staff Wages and Salaries costs is equal to the Clinical Staff Compensation costs as described above multiplied by the Clinical Staff Wages and Salaries costs (described in section III.D.3.a.4. of this final rule) as a percent of Clinical Staff Compensation costs. This same methodology is being used for the FQHC Practitioner Wages and Salaries, Employee Benefits, and Contract Labor, which again reflects the net expenses (Worksheet A, column 7) to address the commenters concerns. Therefore, for this final rule, the Clinical Staff Wages and Salaries cost weight is 12.9 percent, which accounts for 77 percent of the Clinical Staff Compensation cost weight. The Clinical Staff Employee Benefit cost weight is 3.1 percent, which accounts for 18 percent of the Clinical Staff Compensation cost weight. The Clinical Staff Contract Labor cost weight is 0.8 percent, which accounts for 5 percent of the Clinical Staff Compensation cost weight.

(7) Non-Health Staff Compensation Costs

As stated above, the Non-Health Staff Compensation costs are for personnel in general service cost centers including: Employee Benefits department; Administrative & General; Plant Operation & Maintenance; Janitorial; Medical Records; Pharmacy; Medical Supplies; Transportation; and Other General Services.

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Non-Health Staff Compensation costs using net expenses (that is, costs after reclassifications and adjustments) as the estimated share of compensation costs from Worksheet A, column 7 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Since the net expenses for the General Service Cost centers include both compensation and other costs we estimate the share of net expenses for each general service cost center that reflects compensation costs.

First, we estimate a share of Non-Health Staff Wages and Salaries costs for each general service cost center as reported on Worksheet A, column 1 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12 divided by Worksheet A, column 1 and 2 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Then, we multiply the Non-Health Staff Net expenses (that is, costs after reclassifications and adjustments) by the Non-Health Staff Wages and Salaries share to derive estimated Non-Health Staff Wages and Salaries for each general service cost center (lines 3–7 and lines 9–12).

Second, we estimate Non-Health Staff Employee Benefit costs by multiplying the Non-Health Staff Wages and Salaries costs (step one) by the facility benefit to salary ratio. Finally, we add the derived Non-Health Staff Wages and Salaries costs and the derived Non-Health Staff Employee Benefits costs for each general service cost center (line 3–7 and lines 9–12). The results is the 2017-based FQHC market basket Non-health Staff Compensation cost weight of 27.2 percent compared to the proposed rule with 25.4 percent.

(8) Pharmaceuticals Costs

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are calculating Pharmaceuticals costs as the non-compensation costs for the pharmacy cost center. We define this as Worksheet A, column 7, line 9 less derived Pharmacy compensation costs. Similar to the methodology used for the Non-Health Staff compensation, we derive estimated Pharmacy compensation costs.

First we derive the share of pharmacy wages and salaries as Worksheet A, column 1, line 9 divided by the sum of Worksheet A, Column 1 & 2, for line 9. Then, we multiply the pharmacy wages and salaries share by pharmacy net expenses (Worksheet A, column 7, line 9).

Second, we estimate Pharmacy employee benefits by multiplying the derived Pharmacy wages and salaries by the facility benefit to salary ratio. The derived Pharmacy compensation costs are equal to the sum of the estimated pharmacy wages and salaries and pharmacy benefits costs. Using this finalized methodology, we derive a 2017-based FQHC market basket Pharmacy cost weight of 2.4 percent compared to the proposed rule with 3.9 percent.

(9) Medical Supplies

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are calculating medical supplies costs as the non-compensation costs for

the Medical Supplies costs center. We define this as Worksheet A, column 7, line 10 less derived Medical Supplies compensation costs. Similar to the methodology used for the Non-Health Staff compensation, we estimate Medical Supplies compensation costs.

First, we derive the share of medical supplies wages and salaries as Worksheet A, column 1, line 10 divided by the sum of Worksheet A, Column 1 & 2, line 10. Then, we multiply the medical supplies wages and salaries share by the medical supplies net expense (Worksheet A, column 7, line 10).

Second we estimate Medical Supplies employee benefits by multiplying the derived Medical Supplies wages and salaries by the facility benefit to salary ratio. The derived Medical Supplies compensation costs are equal to the sum of the estimated medical supplies wages and salaries and medical supplies benefits costs. Using this finalized methodology, we derive a 2017-based FQHC market basket Medical Supplies cost weight of 2.2 percent compared to the proposed rule with 2.4 percent.

(10) Fixed Capital

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining fixed capital costs to be equal to costs reported on Worksheet A, line 1, column 7 of the Medicare Cost Report. Using this finalized methodology, we derive a 2017-based FQHC market basket fixed capital cost weight of 4.4 percent compared to the proposed rule with 4.6 percent.

(11) Moveable Capital Costs

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining moveable capital costs to be equal to the capital costs as reported on Worksheet A, line 2, column 7. Using this finalized methodology, we derive a 2017-based FQHC market basket Moveable Capital cost weight of 2.0 percent compared to the proposed rule with 1.9 percent.

b. Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we proposed to trim the data for outliers. For each of the eleven major cost categories, we proposed to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of FQHC providers. For the 2017-based FQHC market basket (similar to the 2013-based FQHC market basket), we proposed that total Medicare allowable costs would be equal to the total costs as reported on Worksheet A, columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, column 1, lines 23 through 36; and Worksheet S3 Part II, columns 1 and 2, lines 2 through 14. In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Medicare allowable costs for freestanding FQHC facilities as the total net expenses (after reclassifications and adjustments) reported on: Worksheet A, column 7, for lines 1 through 7, lines 9 through 12; and lines 23 through 36. These are the same cost centers that were used in the proposed market basket for which the commenters agreed was appropriate.

For the FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Pharmaceuticals, Medical Supplies, Fixed Capital, and Moveable Capital cost weights, after excluding cost weights that are less than or equal to zero, we proposed to then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the exclusion of outliers. A 5 percent trim is the standard trim applied to the mean cost weights in all CMS market baskets and is consistent with the trimming used in the 2013-based FQHC market basket. After the outliers have been excluded, we add the costs for each category across all remaining providers. We proposed to then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2017-based FQHC market basket for the given category. This trimming process is done for each cost weight separately. We did not receive any comments on this proposal, and therefore, we are going to use the same trimming methodology to remove outliers as proposed but with the revised cost weights reflecting the new methodology in response to public comment.

Finally, we proposed to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the eleven major cost categories listed. We referred readers to Table 35 for the resulting cost weights for these major cost categories.

Table 35 also shows the proposed and final 2017-based FQHC market basket cost weights compared to the 2013-based FQHC market basket cost weights.

TABLE 35: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	Final 2017-Based FQHC Cost Report Weights (Percent)	Proposed 2017-Based FQHC Cost Report Weights (Percent)	2013-Based FQHC Market Basket (Percent)
FQHC Practitioner Compensation*	*28.4*	*30.0*	31.7
FQHC Practitioner Wages & Salaries	19.4	20.5	-
FQHC Practitioner Employee Benefits	4.5	4.5	-
FQHC Practitioner Contract Labor	4.6	4.9	-
Clinical Staff Compensation*	*16.8*	*16.2*	9.5
Clinical Staff Wages & Salaries	12.9	12.4	-
Clinical Staff Employee Benefits	3.1	3.0	-
Clinical Staff Contract Labor	0.8	0.8	-
Non-Health Staff Compensation*	27.2	25.4	27.4
Pharmaceuticals	2.4	3.9	5.1
Medical Supplies	2.2	2.4	-
Fixed Capital	4.4	4.7	4.5
Moveable Capital	2.0	1.9	1.7
All Other (Residual)	16.5	15.5	20.1

*Employee Benefits weight from the 2013-based FQHC Market Basket (10.7 percent), which was derived from the Medicare Cost Reports (81 FR 80395) and distributed across the three compensation categories: FQHC Practitioner, Clinical Staff, and Non-Health Staff based on the relative shares of each category.
Note: Totals may not sum to 100.0 due to rounding

The total compensation cost weight of 72.5 percent (sum of FQHC Practitioner Compensation, Clinical Compensation, Non-health Staff Compensation) calculated from the Medicare cost reports for the final 2017-based FQHC market basket is approximately 4.0 percentage point higher than the total compensation cost weight for the 2013-based FQHC market basket (68.6 percent). The 2017-based cost weight for FQHC Practitioner Compensation are about 3 percentage points lower compared to the 2013-based FQHC market basket, while the clinical staff compensation cost weight is about 7 percentage points higher. Part of the reason for the shift in the weights between compensation categories may be due to the change to the FQHC Medicare cost report form. On the 1992 Medicare cost report form (used for the 2013-based FQHC market basket), there were four open ended ''fill-in'' categories for healthcare staff costs and costs under agreement. Since we were unable to determine what specific category the ''other health care staff'' costs should be allocated to (that is, either FQHC practitioner, or clinical staff) we used a methodology where we applied the expenses for the ''other health care staff costs'' between the categories for FQHC practitioner and clinical staff, based on the relative shares of expenses for both categories, excluding the open-ended fill in lines of Worksheet A, lines 9–11 and line 15. This may have resulted in an over allocation of some of the 2013 expenses to the FQHC Practitioner category relative to the clinical staff. On the 2014 Medicare cost report form, there is no longer an ambiguous category for other direct patient care staff costs.

The final 2017-based Pharmaceuticals cost weight is roughly 2.7 percentage points lower than the cost weight in the 2013-based FQHC market basket. The pharmaceutical costs included in the weight for 2017-based FQHC market basket includes only non-compensation costs reported in Pharmacy (under general services). We believe the cost share is lower with the new data because there is more specificity on where to report reimbursable and non-reimbursable drugs. Additionally, using the net expense data (that is after reclassifications and adjustments) results in a lower share for pharmacy expenses relative to if total costs are used. This implies that there are notable reclassifications and adjustments to the Medicare Allowable pharmacy expenses as mentioned by commenters as a reason for the concern for not using Net expense data.

As we did for the 2013-based FQHC market basket, we proposed to allocate the contract labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs comprise both Wages and Salaries and Employee Benefits for both FQHC Practitioners and Clinical Staff. The contract labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This rounded percentage based on the proposed cost weights was 82 percent for FQHC Practitioners and 80 percent for clinical staff. Therefore, we proposed to allocate 82 percent of the FQHC Practitioner Contract Labor cost weight to the FQHC Practitioner Wages and Salaries cost weight and 18 percent to the FQHC Practitioner Employee Benefits cost weight. Similarly, we proposed to allocate 80 percent of the clinical staff contract labor cost weight to the Clinical Staff Wages and Salaries cost weight and 20 percent to the clinical staff employee benefits cost weight. In response to comment, in the final 2017-based FQHC market basket, we are allocating 81 percent of the FQHC Practitioner Contract Labor to FQHC Practitioner Wages and Salaries and 19 percent to the FQHC Practitioner Employee Benefits. We are also allocating 81 percent of the Clinical Staff Contract Labor to Clinical Staff Wages and Salaries and 19 percent to

the Clinical Staff Employee Benefits. We refer readers to Table 36 that shows the final Wages and Salaries and Employee Benefits cost weights after Contract Labor cost weight allocation for the final 2017-based FQHC market basket.

TABLE 36: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	Final 2017-Based FQHC Practitioner	Final 2017-Based Clinical Staff	Proposed 2017-Based FQHC Practitioner	Proposed 2017-Based Clinical Staff
Wages and Salaries	23.1	13.6	24.6	13.0
Employee Benefits	5.4	3.3	5.4	3.2
Compensation	28.4	16.8	30.0	16.2

*Totals may not sum due to rounding

c. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2017 Medicare cost report data into more detailed cost categories, we proposed to use the 2012 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 621100, Offices of Physicians, published by the Bureau of Economic Analysis (BEA). We note that the BEA benchmark I–O data is used to further disaggregate residual expenses in other CMS market baskets. Therefore, we noted that we believe the data from this industry are the most technically appropriate for disaggregation of the residual expenses since both physician offices and FQHCs provide similar types of care. These data are publicly available at *https://www.bea.gov/industry/input-output-accounts-data*. For the 2013-based FQHC market basket, we used the relative shares of certain categories from the 2006-based MEI (81 FR 80396).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[53] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2012 Benchmark I–O data forward to 2017 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2017. These resulting 2017 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2017-based FQHC market basket. For example, the cost for Medical Equipment represents 7.2 percent of the sum of the ''All Other'' 2012 Benchmark I–O Offices of Physicians Expenditures inflated to 2017. Therefore, the proposed Medical Equipment cost weight represents 7.2 percent of the proposed 2017-based FQHC market basket's ''All Other'' cost category (16.5 percent), yielding a Medical Equipment cost weight of 1.2 percent in the 2017-based FQHC market basket (0.072×16.5 percent = 1.2 percent).

Using this methodology, we proposed to derive six detailed FQHC market basket cost category weights from the proposed 2017-based FQHC market basket residual cost weight (15.5 percent). These categories are: (1) Utilities; (2) Medical Equipment; (3) Miscellaneous Products; (4) Professional, Scientific, and Technical Services; (5) Administrative Support and Waste Management Services; (6) All Other Services. We note that for the 2013-based FQHC market basket, we had Telephone and Postage cost weights. For the 2017-based FQHC market basket, we proposed to include Telephone and Postage costs in the Miscellaneous Products cost weight due to the small amount of costs in this category (each were less than .05 percent).

We did not receive any comments on our proposed derivation of the detailed operating cost weights. Therefore, we are finalizing our methodology as proposed. In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, the ''All Other'' residual cost weight was revised from the proposed rule to reflect the revised methodology as explained in section III.D.3.a of this final rule. The ''All Other'' residual cost weight is 16.5 percent compared to the proposed 15.5 percent weight.

d. 2017-Based FQHC Market Basket Cost Categories and Weights

Table 37 shows the cost categories and weights for the Final 2017-based FQHC market basket compared to the proposed 2017-based FQHC market basket and the 2013-based FQHC market basket.

[53] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

TABLE 37: Final 2017-Based FQHC Market Basket Cost Weights Compared to Proposed 2017-Based FQHC Market Basket, and the 2013-Based FQHC Market Basket Cost Weights

Cost Category	Final 2017-based FQHC Market Basket Cost Weight	Proposed 2017-based FQHC Market Basket Cost Weight	2013-based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**	**100.0**
Compensation	**72.5**	**71.6**	**68.7**
FQHC Practitioner Compensation	**28.4**	**30.0**	**31.7**
FQHC Practitioner Wages and Salaries	23.1	24.6	-
FQHC Practitioner Employee Benefits	5.4	5.4	-
Clinical Staff Compensation	**16.8**	**16.2**	**9.5**
Clinical Staff Wages and Salaries	13.6	13.0	-
Clinical Staff Employee Benefits	3.3	3.2	-
Non-Health Staff Compensation	**27.2**	**25.4**	**27.4**
All Other Products	**8.5**	**10.0**	**16.1**
Pharmaceuticals	2.4	3.9	5.1
Utilities	0.6	0.5	1.4
Telephone	-	-	1.7
Postage	-	-	1.0
Medical Equipment	1.2	1.1	2.2
Medical Supplies	2.2	2.4	2.0
Miscellaneous Products	2.2	2.1	2.8
All Other Services	**12.6**	**11.8**	**9.0**
Professional, Scientific, and Technical Services	6.4	6.0	2.9
Administrative and Facilities Support Services	1.7	1.6	3.4
All Other Services	4.5	4.2	2.7
Capital-Related Costs	**6.4**	**6.6**	**6.1**
Fixed Assets	4.4	4.7	4.5
Movable Equipment	2.0	1.9	1.7

Note: Totals may not sum due to rounding.

4. Selection of Price Proxies

After developing the cost weights for the 2017-based FQHC market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on U.S. Bureau of Labor Statistics (BLS) data, as they produce indexes that best meet the criteria of reliability, timeliness, availability, and relevance, and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Industry Classification System (NAICS) and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the

underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

• *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

• *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

The CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 38 lists all price proxies we proposed to use in the 2017-based FQHC market basket. Below is a detailed explanation of the price proxies we proposed for each cost category, many of which are the same as those used for the 2013-based FQHC market basket.

a. Price Proxies for the 2017-Based FQHC Market Basket

(1) FQHC Practitioner Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians or FQHC Practitioners, and therefore, we proposed to use an index that is based on professionals that receive advanced training similar to those performing at the FQHC Practitioner level of care. This index is consistent with the price proxy used to measure wages and salaries inflation pressure for physicians own time in the Medicare Economic Index (MEI) and is based on the MEI technical panel recommendation from 2012 (78 FR 74266 through 74271). Additionally, this price proxy is consistent with the proxy used for FQHC practitioner compensation in the 2013-based FQHC market basket (81 FR 80397). We noted that the 2013-based FQHC market basket has a single cost category for Total Compensation reflecting both wages and salaries and employee benefits costs for FQHC Practitioners and this single compensation category uses the similar price proxy, the ECI Total Compensation for Private Industry Workers in Professional and Related, reflecting both types of compensation costs together rather than separately (81 FR 80397).

(2) FQHC Practitioner Employee Benefits

We proposed to use the ECI for Total Benefits for Private Industry Workers in Professional and Related to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. The 2013-based FQHC market basket did not include a separate category for FQHC Practitioner employee benefit costs.

(3) Clinical Staff Wages and Salaries

We proposed to use the ECI for Wages and Salaries for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU1026200000000I) to measure the price growth of this cost category. This cost category consists of wage and salary costs for Nurses, Laboratory Technicians, and all other healthcare staff not included in the FQHC Practitioner compensation categories. Based on the clinical staff composition of these workers, we noted that we believe that the ECI for health-related workers is an appropriate proxy to measure wage and salary price pressures for these workers. We noted that the 2013-based FQHC market basket has a single cost category for Total Compensation reflecting both wages and salaries and employee benefits costs for Clinical Staff and this single compensation category uses the similar price proxy, the ECI Total Compensation for all Civilian Workers in Health Care and Social Assistance, reflecting both types of compensation costs together rather than separately (81 FR 80398).

(4) Clinical Staff Employee Benefits

We proposed to use the ECI for Total Benefits for all Civilian Workers in Health Care and Social Assistance to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. The 2013-based FQHC market basket did not include a separate category for Clinical Staff employee benefit costs.

(5) Non-Health Staff Compensation

We proposed to continue to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. The Non-health Staff Compensation cost weight is predominately attributable to administrative and facility type occupations, as reported in the data from the Medicare cost reports. This is the same price proxy used in the 2013-based FQHC market basket (81 FR 80398).

(6) Pharmaceuticals

We proposed to continue to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as 2014-based Inpatient Prospective Payment System and 2014-based Skilled Nursing Facility market baskets. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(7) Utilities

We proposed to continue to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(8) Medical Equipment

We proposed to continue to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(9) Medical Supplies

We proposed to continue to use a 50/50 blended index that comprises the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We noted that we believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages,

dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we proposed to combine the two aforementioned indexes to reflect those modes of purchase. This is the same blended price proxy used in the 2013-based FQHC market basket (81 FR 80398).

(10) Miscellaneous Products

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We noted that we believe that using the CPI for All Items Less Food and Energy is appropriate as it reflects a general level of inflation. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(11) Professional, Scientific, and Technical Services

We proposed to continue to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(12) Administrative and Facilities Support Services

We proposed to continue to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(13) All Other Services

We proposed to continue to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(14) Fixed Capital

We proposed to continue to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category (81 FR 80398). This is the same price proxy used in the 2013-based FQHC market basket. We noted that we believe this continues to be the most appropriate price proxy since fixed capital expenses in FQHCs should reflect inflation for the rental and purchase of business office space.

(15) Moveable Capital

We proposed to continue to use the PPI Commodities for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical moveable equipment. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

We did not receive any comments on the proposed price proxies in the 2017-based FQHC market basket, and therefore, we are finalizing this proposal without modification.

c. Summary of Price Proxies of the Final 2017-Based FQHC Market Basket

Table 38 shows the cost categories and associated price proxies for the 2017-based FQHC market basket.

TABLE 38: Cost Categories and Price Proxies for the Final 2017-Based FQHC Market Basket

Cost Description	Price Proxies
FQHC Practitioner Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Professional and Related
FQHC Practitioner Employee Benefits	ECI for Total Benefits for Private Industry Workers in Professional and Related
Clinical Staff Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Health care and Social Assistance
Clinical Staff Employee Benefits	ECI for Total Benefits for All Civilian Workers in Health Care and Social Assistance
Non-Health Staff Compensation	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
Pharmaceuticals	PPI Special Index for Pharmaceuticals for Human Use, Prescription
Utilities	CPI-U for Fuels and Utilities
Medical Equipment	PPI Commodity Index for Surgical and Medical Instruments
Medical Supplies	Composite: PPI Commodity Index for Medical and Surgical Appliances and Supplies (50%) and CPI for Medical Equipment and Supplies (50%)
Miscellaneous Products	CPI-U for All items less food and energy
Professional, Scientific, and Technical Services	ECI for Total compensation for Private industry workers in Professional, Scientific, and Technical Services
Administrative and Facilities Support Services	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
All Other Services	ECI for Total Compensation for Private Industry Workers in Service Occupations
Fixed Capital	PPI Industry Index for Lessors of Nonresidential Buildings
Movable Capital	PPI Commodity Index for Machinery and Equipment

Comment: Several commenters applauded CMS, both for implementing an FQHC-specific market basket adjuster, per section 1834(o)(2)(B) of the Act, and for taking the initiative to rebase the market basket percentage, effective in 2021, using more recent cost data. One commenter stated they had been a long-term supporter of the FQHC specific market basket serving as the annual update method for health centers, in both Medicare and Medicaid. The commenter stated that they believe that the alternative, the MEI, is outdated and does not appropriately capture the services that health centers provide and therefore is not an appropriate update factor. The commenters appreciated that CMS updates the calculation periodically so that the cost weights reflect a current mix of goods and services purchased in providing FQHC services. The commenters stated that they did not have concerns with the overall structure of the calculation, and they noted that they believe the use of a fixed-weight, Laspeyres-type price index that uses cost weights and price proxies (based on publicly available cost indexes) is a reasonable way to measure the increase in the price over time of goods and services needed to furnish FQHC services.

Response: We appreciate the commenters' support of the FQHC market basket and the periodic rebasing and revision of the market basket to account for changes in the mix of goods and services purchased in providing FQHC services as well as the general methodological approach of using Medicare Cost Report data, a Laspeyres-type index formula, and the use of publically available price proxies when available and appropriate.

In response to public comment, we are finalizing the 2017-basd FQHC market basket with modification effective with CY 2021 FQHC PPS update.

5. CY 2021 Productivity Adjusted Market Basket Update for FQHCs

For CY 2021 (that is, January 1, 2021 through December 31, 2021), we proposed to use the 2017-based FQHC market basket increase factor to update the PPS payments to FQHCs. Consistent with CMS practice, we estimated the market basket update for the FQHC PPS based on the most recent forecast from IGI. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multifactor productivity (MFP). We proposed to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2021 FQHC update would be based on the four-quarter moving-average percent change of the 2017-based FQHC market basket through the second quarter of 2020 (based on the final rule's statutory publication schedule). At the time of the proposed rule, we did not have the second quarter of 2020 historical data, and therefore, we proposed to use the most recent projection available at the time.

Based on IGI's third quarter 2020 forecast with historical data through the second quarter of 2020, the final 2017-based FQHC market basket increase factor for CY 2021 is 2.4 percent. For comparison, the 2013-based FQHC market basket update is projected to be 2.3 percent in CY 2021; this estimate is based on IGI's third quarter 2020 forecast (with historical data through the second quarter of 2020). We note that the forecast used for the proposed market basket update was developed prior to the economic impacts of the COVID–19 pandemic. The lower final update (2.4 percent) for CY 2021 relative to the proposed rule (2.5 percent) is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets have been significantly impacted during the recession that started in February 2020.

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. We have included a productivity adjustment to the FQHC PPS annual payment update since implementation of the FQHC PPS (81 FR 80393) and we proposed to continue to include a productivity adjustment to the 2017-based FQHC market basket. We proposed to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity (MFP), which is the same measure of MFP applied to other CMS Market Basket updates including the MEI. The BLS publishes the official measure of private nonfarm business MFP (see *http://www.bls.gov/mfp* for the published BLS historical MFP data). For the final FQHC market basket update, we proposed to use the most recent historical estimate of annual MFP as published by the BLS. Generally, the most recent historical MFP estimate is lagged 2 years from the payment year.

Therefore, we proposed to use the 10-year moving average percent change in annual private nonfarm business MFP through 2019 as published by BLS in the CY 2021 FQHC market basket update. We noted that MFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of development of the proposed rule the 2019 MFP was not yet published by BLS, we proposed to use IGI's first quarter 2020 forecast of MFP. A complete description of the MFP projection methodology is available at *http://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgram RatesStats/MarketBasketResearch.html*.

Using IGI's first quarter 2020 forecast, the productivity adjustment for CY 2021 (the 10-year moving average of MFP for the period ending CY 2019) was projected to be 0.6 percent. Therefore, the proposed CY 2021 productivity-adjusted FQHC Market basket update was 1.9 percent, based on IGI's first quarter 2020 forecast with historical data through the fourth quarter of 2019. This reflected a 2.5-percent increase in the proposed 2017-based FQHC market basket and a 0.6-percent adjustment for productivity. Finally, we proposed that if more recent data subsequently become available, we would use such data, if appropriate, to determine the CY 2021 market basket update and the MFP adjustment for the final rule.

For this final rule, as proposed, we are using the latest historical data for MFP as published by the BLS to determine the MFP adjustment. The 10-year moving average percent change in MFP for the period ending CY 2019 as published by BLS is 0.7 percent. Therefore, the final CY 2021 productivity-adjusted FQHC Market basket update is 1.7 percent, based on IGI's third quarter 2020 forecast with historical data through the second quarter of 2020. This reflects a 2.4 percent increase in the final 2017-based FQHC market basket less a 0.7 percentage point adjustment for productivity.

E. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention That Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Opioid overdose deaths continue to impact communities across the United States. In 2018, about 47,000 Americans died as a result of an opioid overdose, where 32 percent of these deaths involved a prescription opioid.[54] In addition to the risk of death from overdose, opioids carry a number of other health risks, including respiratory

[54] Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020;69:290–297.

depression, drowsiness, confusion, nausea, increased drug tolerance, and physical dependence. An estimated 1.4 million people in the United States have substance use disorders (SUDs) involving prescription opioid pain relievers.[55]

CMS has a vital role in addressing opioid use disorder prevention, treatment and recovery. The intent of the SUPPORT Act (Pub. L. 115–271, enacted on October 24, 2018) is to provide for opioid use disorder prevention, treatment and recovery. In section 2002 of the SUPPORT Act, Comprehensive Screening for Seniors, the Congress required the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential SUDs and a review of any current opioid prescriptions. We believe that these provisions are complementary to the existing components of the IPPE and AWV. We proposed to add these new elements to the IPPE and AWV regulations, to draw attention to their importance and fulfil the section 2002 SUPPORT Act requirements. In the CY 2021 PFS proposed rule (85 FR at 50224), we provided background on the IPPE and AWV, discussed how the requirements of the SUPPORT Act are related to the IPPE and AWV, and made proposals to implement these provisions.

1. Background: IPPE and AWV

a. IPPE Required Elements

The IPPE is defined in section 1861(ww) of the Act and codified in regulations at § 410.16. The IPPE must be performed within 1 year after the effective date of a beneficiary's first Medicare Part B coverage period as stated in section 1861(hhh)(4)(G) of the Act. The IPPE includes all of the following services furnished to an eligible beneficiary by a physician or other qualified NPP with the goal of health promotion and disease detection:

- Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in § 410.16.
- Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.
- Review of the beneficiary's functional ability, and level of safety as those terms are defined in § 410.16 based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- An examination to include measurement of the beneficiary's height, weight, body mass index, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.
- End-of-life planning upon agreement with the individual.
- Education, counseling, and referral, as deemed appropriate by the physician or qualified NPP, based on the results of the review and evaluation services described in § 410.16.
- Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits.

b. AWV Required Elements

Section 1861(hhh) of the Act expanded Medicare coverage under Part B to include an AWV effective for services furnished on or after January 1, 2011. We codified the AWV at § 410.15.

The AWV is a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the AWV differ from comprehensive physical examination protocols with which some providers may be familiar since it is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act. The AWV includes a health risk assessment (HRA) and the AWV takes into account the results of the HRA.

The AWV may be performed when the beneficiary is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period and when the beneficiary has not received either an IPPE or AWV within the past 12 months. The AWV may be performed by a physician, NPP (physician assistant, nurse practitioner, or clinical nurse specialist), medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision of a physician. In summary, the first AWV includes the following:

- Review (and administration if needed) of a health risk assessment (as defined in § 410.15).
- Establishment of an individual's medical and family history.
- Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.
- Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.
- Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.
- Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.
- Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in § 410.15 may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- Establishment of the following:

++ A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in § 410.15), health

[55] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–07–01–001, NSDUH Series H–55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/*.

status, screening history, and age-appropriate preventive services covered by Medicare.

++ A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE (as described under § 410.16), and a list of treatment options and their associated risks and benefits.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Any other element determined appropriate through the national coverage determination process.

In summary, subsequent AWVs include the following:

- Review (and administration, if needed) of an updated health risk assessment (as defined in § 410.15).
- An update of the individual's medical and family history.
- An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.
- Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.
- Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.
- An update to the following:

++ The written screening schedule for the individual as that schedule is defined in paragraph (a) of § 410.15 for the first AWV providing personalized prevention plan services.

++ The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of § 410.15.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Any other element determined appropriate through the national coverage determination process.

2. Section 2002 of the SUPPORT Act Requirement

In section 2002 of the SUPPORT Act, sections 1861(ww) and 1861(hhh)(2) of the Act were amended to include a review of any current opioid prescriptions and screening for potential SUDs as elements of the IPPE and AWV, effective January 1, 2020.

3. Revisions to Section 2002 of the SUPPORT Act Requirements

We proposed to add the requirements of section 2002 of the SUPPORT Act to our regulations at §§ 410.15 and 410.16 for the AWV and IPPE, respectively.

Section 2002 of the SUPPORT Act, requires a review of any current opioid prescriptions as part of the IPPE and AWV. Such review includes a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individual's severity of pain and current treatment plan, educational information on non-opioid treatment options, and a referral to a specialist, as appropriate. Section 2002 of the SUPPORT Act also requires adding an element to the IPPE and AWV to include screening for potential SUDs. Along with the screening for SUD, a referral for treatment, as appropriate, was added to the AWV.

The definitions and conditions for and limitations on coverage of the IPPE outlined in § 410.16 includes a review of the beneficiary's medical and social history. The medical history is defined to include a review of current medications, which would include a review of current opioid prescriptions. Furthermore, social history is defined to include, at a minimum, a history of alcohol, tobacco, and illicit drug use. Illicit drug use may include the non-medical use of prescription drugs. The physician or other qualified health professional may then provide education, counseling, and referral, as deemed appropriate, based on the results of the review and evaluation services provided during the IPPE.

The definitions and conditions for and limitations on coverage of the AWV in § 410.15 includes a health risk assessment, which entails an evaluation of psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue. The patient's substance use, if applicable, could be reviewed as part of the health risk assessment. The AWV also covers establishment of, or an update to the individual's medical and family history. The medical history includes medication use, and may have included a review of any opioid prescriptions. The health professional may also establish or update a list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through the initial or subsequent AWV or IPPE, and a list of treatment options and their associated risks and benefits. If the clinician detected, through the above methods for screening, that a patient was at high-risk for SUD in the course of the visit, it would have been appropriate to note in the patient's IPPE written plan or the AWV personalized prevention plan and to have referred the patient for further assessment and treatment.

Awareness of a patient's use of substances, including nonmedical use of prescription drugs and illicit drug use, is an important aspect of the IPPE and AWV. In general, screening for potential SUDs may include screening questions, the use of a specific tool, screening for licit and/or illicit drugs (for example, alcohol, non-medical use of prescription opioids, methamphetamine, heroin, cocaine, and other substances), review of the beneficiary's medical and social history and medical records, or prescription drug monitoring program query when clinically indicated. Given the existing elements of the IPPE and AWV, we do not expect the proposed new regulatory elements to add significant burdens on physicians and practitioners who furnish these services because review of medical and social

history, risk factor identification, education, counseling, and referrals are already fundamental parts of the IPPE and AWV. The new regulatory elements elevate the importance of physicians' and other qualified health professionals' vigilance in identifying and addressing opioid risks and SUDs in Medicare beneficiaries.

4. Summary of Proposed Regulatory Text Changes

We proposed to add elements to our regulations to reflect the provisions of section 2002 of the SUPPORT Act. Consistent with sections 1861(ww) and 1861(hhh)(2) of the Act, we proposed to amend §§ 410.15 and 410.16 by: (1) Adding the term ''screening for potential substance use disorders''; (2) Adding the term ''a review of any current opioid prescriptions'' and its definition; and (3) revising the ''Initial Preventive Physical Examination,'' ''first annual wellness visit providing personalized prevention plan services,'' and ''subsequent annual wellness visit providing personalized prevention plan services''.

a. ''Screening for Potential Substance Use Disorders''

We proposed to revise §§ 410.15 and 410.16 by adding the element ''Screening for Potential Substance Use Disorders'' and describing the requirement as a review of the individual's potential risk factors for SUD and referral for treatment as appropriate.

b. Definition of ''a review of any current opioid prescriptions''

We proposed to revise §§ 410.15 and 410.16 by adding the element ''a review of any current opioid prescriptions'' and defining such term, consistent with section 1861(ww)(4) of the Act, as a review of any current opioid prescriptions, including a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individuals' severity of pain and current treatment plan, the provision of information on non-opioid treatment options, and a referral to a specialist, as appropriate.

c. Proposed Changes to the ''Initial Preventive Physical Examination,'' ''First Annual Wellness Visit'' and ''Subsequent Annual Wellness Visit''

In §§ 410.15 and 410.16, we adopted the components of the IPPE and AWV, consistent with the statutory elements described in sections 1861(ww) and 1861(hhh)(2) of the Act. The IPPE, first and subsequent AWVs are meant to represent a beneficiary visit focused on prevention. Among other things, the IPPE and AWV encourage beneficiaries to obtain the preventive services covered by Medicare that are appropriate for them. First and subsequent AWVs also include elements that focus on the furnishing of personalized health advice and referral, as appropriate, to health education, preventive counseling services, or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions.

We proposed to revise ''initial preventive physical examination,'' ''first annual wellness visit providing personalized prevention plan services,'' and ''subsequent annual wellness visit providing personalized prevention plan services'' by adding:

- In § 410.15(a):

++ A revised paragraph (xi) to the definition of the term ''First annual wellness visit providing personalized prevention plan services,'' and a revised paragraph (ix) to the definition of the term ''Subsequent annual wellness visit'' that would add furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ A new paragraph (xii) to the definition of ''First annual wellness visit providing personalized prevention plan services,'' and a new paragraph (x) to the definition of ''Subsequent annual wellness visit'' that would add screening for potential SUDs including a review of the individual's potential risk factors for SUD and referral for treatment as appropriate.

++ A new paragraph (xiii) to the definition of ''First annual wellness visit providing personalized prevention plan services,'' and a new paragraph (xi) to the definition of ''Subsequent annual wellness visit'' that would add any other element determined appropriate through the national coverage determination process.

- In § 410.16:

++ A revised paragraph (a)(6) to the definition of ''Initial preventive physical examination'' that would include a review of any current opioid prescriptions as that term is defined in this section.

++ A revised paragraph (a)(7) to the definition of ''Initial preventive physical examination'' that would add screening for potential SUDs to include a review of the individual's potential risk factors for SUD and referral for treatment as appropriate.

++ A new paragraph (a)(8) to the definition of ''Initial preventive physical examination'' that would add, education, counseling, and referral, as deemed appropriate by the physician or qualified NPP, based on the results of the review and evaluation services described in this section.

++ A new paragraph (a)(9) to the definition of ''Initial preventive physical examination'' that would include, education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

5. Summary of Public Comments and Responses

We received public comments on the proposed revisions to the requirements under section 2002 of the SUPPORT Act. The following is a summary of the comments we received and our responses.

Comment: The vast majority of commenters supported the proposal to add the requirements of section 2002 of the SUPPORT Act to the regulations at §§ 410.15 and 410.16. Commenters stated that they believe these provisions are complementary to the existing components of the IPPE and AWV and help underscore the importance of prevention and appropriate pain management to stymie the opioid epidemic and detect substance use disorders on a regular schedule. Furthermore, commenters specifically noted that while Medicare has previously emphasized a review of opioid prescriptions is appropriate when collecting a patient's medical and social history within the IPPE and AWV, adding explicit requirements to the regulations regarding opioid prescription review and substance use disorder screening is an important distinction and welcomed by the majority of commenters.

Response: We appreciate the commenters for their support of CMS' efforts to include section 2002 of the SUPPORT ACT in the regulations, which are intended to strengthen provider engagement with patients on appropriate pain management and detection of substance use disorders through the IPPE and AWV.

Comment: According to one commenter a thorough patient assessment for pain and opioid use could take 30–90 minutes and such services should not be part of the AWV or IPPE but should be a separate encounter.

Response: We thank the commenter for highlighting the time it can take for practitioners to appropriately care for patients with pain. Section 2002 of the SUPPORT Act modified the statute to require the addition of certain additional services to the AWV and IPPE. We are not adopting the commenter's suggestion to only pay for these additional services as a separate encounter. We note, however, that there are other opportunities throughout the year outside of the AWV and IPPE, such as E/M services for practitioners to evaluate their patient's pain, consider treatment options and review medications when those services would be reasonable and necessary. In addition, other medically necessary services may be provided on the same date of service as an AWV or IPPE. The Part B deductible and coinsurance or copayment obligations would apply to those additional medically necessary services.

Comment: Some commenters advocated for CMS to increase the payment rate for the AWV and IPPE as a result of these additional required elements. Another commenter stated that the increase in reimbursement for CY 2021 will offset the additional work related to these new requirements. One commenter agreed with CMS that the new elements are aligned and similar to the services already being furnished during the visits and, therefore, would not result in significant added burden. One commenter disagreed with adding the requirements to the AWV and IPPE under section 2002 of the SUPPORT Act because practitioners already address prescriptions and substance abuse issues during these visits and formally including them adds to the paperwork and documentation burden around the visits.

Response: We note that we are required by law through section 2002 of the SUPPORT Act to include the new elements in the AWV and IPPE.

Commenters had various opinions about the appropriate payment rate for the AWV and IPPE with the additional requirements. We note for commenters that in section III.F. of this final rule, we finalized increases in the values of office/outpatient E/M visit codes for CY 2021. The AWV and IPPE services are valued via direct cross walk from the office/outpatient E/M visits. To maintain payment accuracy for the IPPE and the AWV, we finalized adjusting the valuation of these services to reflect the changes in value for E/M services to which they are crosswalked. The payment increase coincides with but is not related to the newly required elements in the AWV and IPPE.

We continue to agree with commenters who believe any additional burden for the new required elements will be minimal and we disagree with commenters that state the additional work will be a significant burden.

Comment: Commenters requested CMS clarify in more detail what is required of practitioners to meet the new required elements of the AWV and IPPE. One commenter specifically requested clarification that if a patient is found at risk for potential substance use disorder after screening that a comprehensive evaluation of that finding is not part of the AWV and IPPE. Another commenter specifically requested clarification around screening.

Response: In an effort to minimize burden and allow flexibility, we have not been more prescriptive with the regulatory language. We believe this allows practitioners to tailor screening to their patients. Medically necessary services beyond the scope of those required as part of the AWV and IPPE, as discussed in an earlier response, may be provided on the same date of service as an AWV or IPPE. The deductible and coinsurance or copayment may apply for these other medically necessary services.

Comment: One commenter asked for clarification on how CMS will enforce these new requirements.

Response: We are planning to enforce the new elements of the AWV and IPPE in the same manner as other services furnished to Medicare beneficiaries.

Comment: One commenter asked CMS to consider the community pharmacy as a provider of screening and referral services.

Response: We appreciate that the commenter is looking to expand access to screening and referral services by including community pharmacies as potential suppliers of these services, but this expansion would exceed the scope of our proposed rule. We did not seek to amend the definition of either ''health professional'' for the AWV or the definition of ''qualified nonphysician practitioner'' for the IPPE. The types of practitioners that are eligible to furnish the AWV are specified in section 1861(hhh)(3) of the Act and defined in our regulations in § 410.15(a). For the IPPE, the practitioners eligible to furnish these services under certain conditions are based on statutory requirements in sections 1861(s)(2)(K) and (ww)(1) of the Act and are defined in our regulations at § 410.16(a).

As a result of the comments, we are finalizing the proposal to add explicit requirements to the regulations regarding opioid prescription review and substance use disorder screening. Specifically, we are adding the requirements of section 2002 of the SUPPORT Act to §§ 410.15 and 410.16 for the AWV and IPPE, respectively.

We did not receive public comments on our proposed regulatory text, and, therefore, we are finalizing the regulatory language as proposed.

F. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for incentive payments made to Medicaid EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of Certified EHR Technology (CEHRT). We have implemented these statutory provisions in prior rulemakings to establish the Medicaid Promoting Interoperability Program.

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act, and the definition of ''meaningful EHR user'' in regulations at § 495.4, one of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. We have taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

In the CY 2020 PFS final rule (84 FR 62568, 62900), we established for 2020 that Medicaid EPs are required to report on any six eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. We also adopted the Merit-based Incentive Payment System (MIPS) requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). We explained that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, the EP may report on any six eCQMs that are relevant.

2. eCQM Reporting Requirements for EPs Under the Medicaid Promoting Interoperability Program for 2021

We annually review and revise the list of eCQMs for each MIPS performance year to reflect updated clinical standards and guidelines. In Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50412), we proposed to amend the list of available eCQMs for the CY 2021 performance period. In Appendix 1 of this final rule, we list the clinical quality measures added (Table Group A), removed (Table Group C), and changed (Table Group D) for the CY 2021 performance period. To keep eCQM specifications current and minimize complexity, we proposed to align the eCQMs available for Medicaid EPs in 2021 with those available for MIPS eligible clinicians for the CY 2021 performance period. Specifically, we proposed that the eCQMs available for Medicaid EPs in 2021 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established for the MIPS CY 2021 performance period.

In previous years, CMS proposals to align the list of eCQMs for MIPS and the Medicaid Promoting Interoperability Program for EPs received positive comments that indicated that alignment between these two programs would help reduce health care provider reporting burden (84 FR 62900; see also 83 FR 59452, 59702). These comments thus suggest that aligning the eCQM lists might encourage EP participation in the Medicaid Promoting Interoperability Program by giving Medicaid EPs that are also MIPS eligible clinicians the ability to report the same eCQMs for both programs. Not aligning the eCQM lists could lead to increased burden, because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program if they opt to report on newly added eCQMs for MIPS. In addition, we believe that aligning the eCQMs available in each program would help to ensure the most uniform application of up-to-date clinical standards and guidelines possible.

As discussed in the CY 2021 PFS proposed rule (85 FR 50227), we anticipate that the proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, particularly in light of our belief that many EPs would report eCQMs to meet the quality performance category of MIPS, and therefore, should be prepared to report on the available eCQMs for 2021. We noted that we expect that the proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2021 to maintain current eCQM lists and specifications.

For 2021, we proposed to again require (as we did for 2020) that Medicaid EPs report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically. This policy of allowing Medicaid EPs to report on any six measures relevant to their scope of practice would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established at § 414.1335(a)(1). MIPS eligible clinicians who elect to submit eCQMs must generally submit data on at least six quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We referred readers to § 414.1335(a) for the data submission criteria that apply to individual MIPS eligible clinicians and groups that elect to submit data with other collection types.

In addition, as we did for 2020, we proposed that for 2021, EPs in the Medicaid Promoting Interoperability Program would be required to report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure). We noted that this policy would improve alignment with the MIPS quality performance category requirements for eligible clinicians using the eCQM collection type. We also proposed that if no outcome or high priority measures are relevant to a Medicaid EP's scope of practice, the clinician may report on any six eCQMs that are relevant, as was the policy in 2020.

In the CY 2020 PFS final rule (84 FR 62899 and 62900), we established the following three methods to identify which of the available measures are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program. We proposed to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2021:

- The same set of measures that are identified as high priority measures for reporting on the quality performance category for eligible clinicians participating in MIPS.
- All e-specified measures from the previous year's core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (Child Core Set) or the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as ''Core Sets'') that are also included on the MIPS list of eCQMs.

Sections 1139A and 1139B of the Act require the Secretary to identify and publish core sets of health care quality measures for child Medicaid and CHIP beneficiaries and adult Medicaid beneficiaries. These measure sets are required by statute to be updated annually and are voluntarily reported by states to CMS. These Core Sets are composed of measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care. The MIPS eCQM list includes several, but not all, of the measures in the Core Sets. Because the Core Sets are released at the beginning of each year, it is not possible to update the list of high-priority eCQMs with those added to the current year's Core Sets.

The eCQMs that would be available for Medicaid EPs to report in 2021, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under the proposal are: CMS2, ''Preventive Care and Screening: Screening for Depression and Follow-Up Plan''; CMS122, ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)''; CMS125, ''Breast Cancer Screening''; CMS128, ''Anti-depressant Medication Management''; CMS136, ''Follow-Up Care for Children Prescribed ADHD Medication (ADD)''; CMS137, ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment''; CMS153, ''Chlamydia Screening for Women''; CMS155, ''Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents''; and CMS165, ''Controlling High Blood Pressure.''

- Through an amendment to § 495.332(f), we gave each state the flexibility to identify which of the eCQMs available for reporting in the Medicaid Promoting Interoperability Program are high priority measures for Medicaid EPs in that state, with review and approval by CMS, through the State Medicaid HIT Plan (SMHP). States are thus able to identify high priority measures that align with their state health goals or other programs within the state.

All eCQMs identified via any of these three methods are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2020. We proposed to use

the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2021. We solicited comments as to whether any of these methods should be altered or removed, or whether any additional methods should be considered for 2021.

Finally, we note that the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program is a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, or falls before a state-specific alternative date prior to October 31, 2021 that is specified in the SMHP, as described in § 495.332(f)(4). This 2021 eCQM reporting period will help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. (See 83 FR 59452, 59704 through 59706).

We received public comments on our proposals for eCQM reporting requirements for EPs under the Medicaid Promoting Interoperability Program for 2021. The following is a summary of the comments we received and our responses.

Comment: The overwhelming majority of commenters supported our proposals and stated that having the same eCQM specifications for the Medicaid Promoting Interoperability program and the MIPS quality performance category requirements for eligible clinicians using the eCQM collection type would indeed reduce the reporting burden on health care providers.

Response: We appreciate the support for our proposals.

Comment: Two commenters noted that the accuracy of eCQM data may be skewed by the timeline necessitating that EPs submit less than a full year of data. They explain that some measures are seasonal, such as those related to influenza, and an EP may report data that do not represent their true level of care over a full year. We also note that both of these commenters supported our proposals.

Response: We acknowledge and understand that reporting periods of less than a year may result in inaccurate or incomplete data. However, the applicable meaningful use requirement to receive an incentive payment is that an EP must simply report the eCQM data to the state. The actual data reported are not used to determine whether an EP is eligible for an incentive payment as a meaningful user of CEHRT. Furthermore, the length of the eCQM reporting period for Medicaid EPs in 2021 is consistent with the length of the eCQM reporting period for 2020. Therefore, health care providers and states should already be aware of issues regarding the statistical validity of partial-year eCQM data. Additionally, when we established the 90-day eCQM reporting period for 2020, we concluded that, generally, the potential data quality issues associated with a shorter eCQM reporting period were outweighed by the benefits of that shorter period to all stakeholders (including to states preparing for the final year of the Medicaid Promoting Interoperability program in 2021), and that establishing 90-day eCQM reporting periods in both 2020 and 2021 might provide better data for comparison across the 2 years (see 84 FR 62901 and 62902). Finally, when we established the 90-day eCQM reporting period for 2021, we noted that it would help ensure that states can make all incentive payments before the statutory deadline (see 83 FR 59705).

Comment: One health care provider commented that the statutory deadline created a shortened time period to update the eCQM specifications in their EHR, which could have cost and staff workload implications. The commenter suggested that we allow EPs the option to report using 2020 specifications or to extend the reporting and payment deadlines.

Response: The December 31, 2021 deadline for payments is statutory and we do not have the authority to alter that deadline. In the 2019 PFS final rule (83 FR 59452), we explained that for states to make payments by that deadline, there must be sufficient time after EHR and eCQM reporting periods end for Medicaid EPs to attest to states, for states to conduct their prepayment processes, and for states to issue payments. Therefore, we amended § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program will be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. We also established that the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program will be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. However, we also allowed states the flexibility to set alternative, earlier final end dates for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from us, through their State Medicaid HIT Plans (SMHP). Any alternative end date for CY 2021 EHR and eCQM reporting periods set by a state may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state. For more information, see our discussion of the EHR and eCQM reporting periods for 2021 at 83 FR 59704–6.

We believe that allowing some EPs to report eCQMs in 2021 according to 2020 specifications, and some to report eCQMs in 2021 according to 2021 specifications, could cause undue confusion about the requirements for providers participating in the Medicaid Promoting Interoperability Program and/or MIPS and increase the administrative burden on states to determine which EPs submitted data in accordance with which specifications. As explained above, we believe that the latest eCQM specifications provide the most up-to-date clinical standards and guidelines. Furthermore, none of the EHR vendors who submitted comments indicated that the accelerated 2021 timeline would pose an obstacle to issuing system updates in time for EPs to attest to meaningful use. For the reasons explained in our proposal, we believe that maintaining a single set of the most up-to-date eCQM specifications for EPs to use in 2021 reduces the burden on EPs who may be reporting to multiple quality programs.

After considering public comments, we are finalizing the proposals in this section as proposed.

G. Medicare Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.) Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare

providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted on February 9, 2018), further amended section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (herein referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31st date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31st COVID–19 IFC''), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268). In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8th and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8th COVID–19 IFC''), we modified Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Refer to the CY 2020 PFS proposed rule for a summary of policies finalized in prior rules (84 FR 40705).

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared Savings Program. These policies included requirements for Shared Savings Program ACOs regarding reporting for the MIPS Quality performance category and a policy that gives ACOs full credit for the MIPS Improvement Activities performance category based on their participation in the Shared Savings Program.

In the CY 2021 PFS proposed rule (85 FR 50229), we explained our belief that the changes we were proposing to the quality reporting requirements under the Shared Savings Program for performance year 2021 and subsequent years would reduce ACO burden by establishing a smaller measure set, out of which ACOs would only be required to actively report 3 measures. This would represent a significant reduction in reporting requirements from the 10 measures on which ACOs are currently required to actively report. Under our proposal, reporting for these measures would begin in January 2022, for the 2021 performance year. We also noted that we believed this timeline would allow organizations sufficient time to prepare to report on the new measure set. In addition, the reporting options for the three ACO-reported measures would leverage existing MIPS collection types and more closely align existing CEHRT and registries used by ACOs and their clinicians, including use of APIs to submit data.

In sections III.G.1 through III.G.4 of this final rule, we summarize and respond to public comments we received on proposed modifications to the Shared Savings Program's policies discussed in section III.G. of the CY 2021 PFS proposed rule (85 FR 50228 through 50252). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the policies addressed in section III.G. of the CY 2021 PFS proposed rule, and will not be addressed in this section of this final rule. As a general summary, in sections III.G.1 through III.G.4 of this final rule we are finalizing the following changes to the Shared Savings Program's regulations to:

- Modify the approach to measuring ACO quality performance under the Shared Savings Program which includes:

++ Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021. Specifically, we are finalizing that:

—For performance year 2021, ACOs will be required to report quality data via the APP, and can choose to report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate 2 measures using administrative claims data.

—For performance year 2022 and subsequent performance years, ACOs will be required to actively report quality data on the 3 eCQM/MIPS CQM measures via the APP. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate two measures using administrative claims data.

++ Revising the Shared Savings Program Quality Performance Standard. ACOs will meet the quality performance standard if:

—For performance years 2021 and 2022, ACOs achieve a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores; and

—For performance year 2023 and subsequent performance years, ACOs achieve a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

++ Changing the methodology for determining shared savings and shared losses based on ACO quality performance.

++ Revising the approach to monitoring ACO quality performance and addressing ACOs that fail to meet the Quality Performance Standard.

++ Updating the process used to validate ACO Quality Data Reporting, where we are finalizing that CMS retains the right to audit and validate quality data reported by an ACO via the APP according to the MIPS DVA process for performance years beginning on or after January 1, 2021.

++ Updating the extreme and uncontrollable circumstances policy as it relates to quality performance.

- Update the definition of primary care services used in beneficiary assignment, and codify in regulations the adjustment that is made to an ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in part 425, subpart E, during an ACO's agreement period, including revisions to the definition of primary care services at § 425.402(c).

- Revise the repayment mechanism arrangement policy in the following manner:

++ To reduce the repayment mechanism amount for certain ACOs entering an agreement period starting on January 1, 2022, and in subsequent years.

++ To allow a one-time opportunity for certain ACOs that renewed for a new agreement period beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of their existing repayment mechanisms.

++ To permit a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, to use its existing repayment mechanism to support its new agreement period, in a similar manner as applies to renewing ACOs.

In section III.G.5. of this final rule, we summarize and respond to public comments received in response to the May 8th COVID–19 IFC, and discuss our final policies after taking into consideration the public comments.

1. Quality and Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule establishing the Shared Savings Program, we adopted a quality measure set spanning four domains: patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). Since then, we have updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, and 83 FR 59707 through 59715 respectively).

As we stated in the November 2011 final rule (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality

health care at the individual and population levels, with a focus on outcomes. In the CY 2019 PFS final rule, we finalized that for performance years (or a performance period) starting in 2019 and subsequent years, 23 quality measures would be used to determine ACO quality performance (83 FR 59707 through 59715). The information used to determine ACO performance on these quality measures is submitted by the ACO through the CMS Web Interface, calculated by us from administrative claims data, and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey.

Eligible clinicians who are participating in an ACO and who are subject to MIPS (MIPS eligible clinicians) are currently scored under the APM scoring standard under MIPS (81 FR 77260). These MIPS eligible clinicians include any eligible clinicians who are participating in an ACO in a track, or payment model within a track (Track 1 and Levels A through D of the BASIC track) of the Shared Savings Program that is not an Advanced APM, as well as those MIPS eligible clinicians participating in an ACO in a track, or payment model within a track (Track 2, Level E of the BASIC track, and the ENHANCED track, or the Medicare ACO Track 1+ Model (Track 1+ Model)) that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS.

b. Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs

As provided in section 1899(d)(2) of the Act and § 425.502(a) of the Shared Savings Program regulations, ACOs must meet a quality performance standard to qualify to share in savings. In the CY 2017 PFS final rule, we finalized revisions to § 425.502 related to the quality performance standard and minimum attainment, including clarifying that the quality performance standard is the overall standard the ACO must meet to qualify to share in savings; defining the minimum attainment level for pay for performance measures at the 30th percent or the 30th percentile of the quality performance benchmark and for pay for reporting measures at the level of complete and accurate reporting; specifying that only pay for performance measures are assessed on a sliding scale while pay for reporting measures earn the maximum number of points for a measure when the minimum attainment level is met (81 FR 80492 through 80494).

We explained in the CY 2021 PFS proposed rule (85 FR 50230) that currently, the quality performance standard is based on an ACO's experience in the program rather than its financial track. The quality performance standard is currently defined at the level of full and complete reporting (pay-for-reporting (P4R)) for the first performance year of an ACO's first agreement period under the Shared Savings Program. In the second or subsequent years of the ACO's first agreement period and all years of subsequent agreement periods, quality measures are scored as pay-for-performance (P4P) according to the phase-in schedule for the specific measure and the ACO's performance year in the Shared Savings Program:

- For all performance years, ACOs must completely and accurately report all quality data used to calculate and assess their quality performance.
- CMS designates a performance benchmark and minimum attainment level for each P4P measure and establishes a point scale for the measure. An ACO's quality performance for a measure is evaluated using the appropriate point scale, and these measure-specific scores are used to calculate the final quality score for the ACO.
- ACOs must meet minimum attainment (defined as 30 percent or the 30th percentile of the performance benchmark for P4P measures) on at least one measure in each domain to be eligible to share in any savings generated (§ 425.502(d)(2)(iii)(A)).

In the CY 2020 PFS proposed rule (84 FR 40709 through 40713), we sought comment on how we might align the Shared Savings Program quality reporting requirements and scoring methodology more closely with the MIPS quality reporting and scoring methodology. We discussed utilizing the MIPS Quality performance category score to adjust shared savings and shared losses under the Shared Savings Program, as applicable. We also sought comment on a possible new approach to determining the threshold for minimum attainment. Under this potential policy, minimum attainment would continue to be defined as complete and accurate reporting for ACOs in their first performance year of their first agreement period, while a MIPS Quality performance category score at or above the 4th decile across all MIPS Quality performance category scores would be required for ACOs in all other performance years under the Shared Savings Program. ACOs with MIPS Quality performance category scores below the 4th decile of all MIPS Quality performance category scores would not meet the quality performance standard for the Shared Savings Program, and thus, would not be eligible to share in savings or would owe the maximum shared losses, if applicable. In addition, we sought comment on a potential policy under which ACOs with quality scores below the 4th decile of all MIPS Quality performance category scores would be subject to compliance actions and possible termination.

We noted in the CY 2021 PFS proposed rule (85 FR 50230) that the majority of feedback received in response to our comment solicitation did not support this approach as it would hold ACOs to a higher standard to be eligible to share in savings, if earned. In addition, commenters that opposed aligning the Shared Savings Program quality score with the MIPS Quality performance category score, stated that significant restructuring of the Shared Savings Program quality performance requirements would introduce more confusion for ACOs that are also transitioning into new tracks under the December 2018 final rule. Commenters also expressed concern regarding the uncertainty associated with such an approach, as we had also proposed extensive revisions to MIPS as the program transitions to MIPS Value Pathways. Furthermore, commenters noted that ACOs are unique in that they are responsible for the total cost of care of their beneficiaries and should not be compared to clinicians in MIPS who are not participating in total cost of care programs.

In the CY 2021 PFS proposed rule (85 FR 50230 and 50231), we acknowledged the commenters' concerns, but noted that section 1899(b)(3)(C) of the Act not only gives us discretion to establish quality performance standards for the Shared Savings Program, but also indicates that we should seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing quality of care. The Shared Savings Program is now in its eighth performance year, and 85 percent of ACOs participating in the program are considered PY3 ACOs for purposes of quality reporting, with 65 percent of those ACOs participating in a second or subsequent agreement period. In light of the maturity of the program and consistent with section 1899(b)(3)(C) of the Act, we stated that we believe that it is appropriate to require a higher standard of care in order for ACOs to continue to share in any savings they achieve. In addition, holding ACOs to a higher standard is in line with CMS' goals of incentivizing

value-based care and driving the Medicare system to greater value and quality. However, we explained that after taking into consideration the stakeholder feedback, we had also considered ways to reduce reporting burden, offer more flexibility in the way quality data can be reported and submitted, and create a more meaningful measure set that would focus on population health measures and be more outcome-oriented, while also including patient experience of care metrics.

We stated in the CY 2021 PFS proposed rule (85 FR 50231) that although the Alternative Payment Model Performance Pathway (APP) was designed for all MIPS APMs, it is also responsive to the concerns raised by commenters in their responses to our solicitation in the CY 2020 PFS proposed rule, while still taking into consideration the maturity of the Shared Savings Program, ACOs' quality performance over time, and the intent of section 1899(b)(3)(C) of the Act. The APP contains a narrower measure set than has previously been used for Shared Savings Program quality measurement, 6 measures versus the current 23 scored measures, and is specifically intended for use in APMs and population health. The design of the APP aligns with stakeholder interests expressed through comments on our solicitation about aligning the Shared Savings Program with MIPS in the CY 2020 PFS proposed rule. These comments suggested adopting a smaller, more focused measure set in recognition of the fact that APM Entities are incentivized through the terms of the respective APMs to improve value. The measure set proposed for the APP aligns with the Meaningful Measures framework by identifying measures that address the highest priorities for quality measurement and improvement, while also reducing reporting burden, promoting alignment of measures and consolidation of reporting requirements across CMS programs moving payment toward value, and identifying consumers' key quality performance metrics. We noted that the measures proposed for inclusion in the APP measure set encompass the meaningful measure domains of patient voice, wellness and prevention, seamless communication, chronic disease management, and behavioral health. For these reasons, we stated in the CY 2021 PFS proposed rule that we believe that the proposed APP, along with the narrower measure set, which comprises it, would be appropriate to assess the quality performance of Shared Savings Program ACOs.

The construction of the proposed APP for Shared Savings Program ACOs and the proposed measures within it were described in detail in section III.G.1.b.(1) of the CY 2021 PFS proposed rule (85 FR 50231 through 50235). A detailed discussion of the proposal for use of the APP for MIPS APMs more generally can be found in section IV.A.3.b. of the CY 2021 PFS proposed rule (85 FR 50285 through 50288).

(1) APM Performance Pathway for Shared Savings Program ACOs

In section III.G.1.b.(1) of the CY 2021 PFS proposed rule (85 FR 50231 through 50235), we described the proposals related to the APM Performance Pathway for Shared Savings Program ACOs. In response to the stakeholder feedback and in order to improve alignment and integration with the Quality Payment Program policies and operations, align with CMS' Meaningful Measure Framework, increase participation in APMs and Advanced APMs by reducing reporting burden, and raise the quality performance standard under the Shared Savings Program, we proposed to revise the Shared Savings Program quality performance standard effective for performance year 2021 and subsequent performance years. We explained that the proposed revision would align the Shared Savings Program quality performance standard with the proposed APP under the Quality Payment Program as participants in the Shared Savings Program would be required to report quality for purposes of the Shared Savings Program via the APP, which was described in more detail in section IV.A.3.b. of the CY 2021 PFS proposed rule (85 FR 50285 through 50288).

At a high level, we proposed that the APP would replace the current Shared Savings Program quality measure set to streamline reporting requirements for Shared Savings Program ACOs and would be a complementary path to the MIPS Value Pathways. The APP is designed to reduce reporting burden, create new scoring opportunities for participants in MIPS APMs, and encourage participation in APMs.

Under this proposed new approach, ACOs would only need to report one set of quality metrics that would satisfy the reporting requirements under both MIPS and the Shared Savings Program. There would not be separate quality reporting requirements under the Shared Savings Program, as under the proposed new approach the quality measures reported for purposes of the APP would also be used to determine the quality performance of the ACO for purposes of the Shared Savings Program, which is used for purposes of calculating shared savings and also shared losses, where applicable. We stated that we believe this approach of streamlining the quality reporting requirements under the Shared Savings Program while maintaining alignment with the Quality Payment Program will help ACOs and their participating providers and suppliers dedicate their finite resources to engaging in efforts to improve quality and reduce costs for their assigned beneficiary population. In addition, we explained that using a single methodology to measure quality performance under both the Shared Savings Program and MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients. It would also reduce burden as ACOs would be able to track to a smaller set of measures under a unified scoring methodology.

We received many public comments on the proposals to apply the APP to determine the quality performance of Shared Savings Program ACOs. The following is a summary of the comments we received and our responses.

Comment: We received many comments on the proposal to apply the APP to determine quality performance of Shared Savings Program ACOs. Supportive commenters noted that this proposal would align reporting requirements for MIPS and the Shared Savings Program, shift the focus from process measures to clinical outcomes, move toward eliminating unnecessary and inappropriate measures, focus on appropriate measures for ACO accountability, and provide entities more flexibility for reporting and allow MIPS eligible clinicians the option of reporting quality data separately from the ACO for purposes of MIPS scoring. Further, one commenter noted that alignment between MIPS and quality reporting requirements for Advanced APMs would create a better glidepath for healthcare providers looking to transition away from fee-for-service. Additionally, commenters noted that streamlined reporting requirements, a smaller set of measures, and a unified scoring methodology for the Shared Savings Program and MIPS would result in reduced burden for ACOs and allow ACOs to dedicate limited resources toward improving care for beneficiaries. One commenter noted that alignment of Shared Savings Program quality reporting requirements under the APP with reporting requirements under the MIPS program would minimize the

barrier for practices transitioning to an APM.

However, a majority of commenters expressed concerns about the proposal. The most common concerns were the time, effort, and cost involved in transitioning to a new measure set, new reporting mechanisms, and all-payer reporting, with potentially unintended negative impacts on quality, particularly during a time when healthcare organizations are impacted by the PHE for COVID–19. Specific concerns included the time needed to identify and implement new data collection mechanisms, modify operational workflows and clinical strategies to align with the six APP quality measures, secure new technology capabilities, assess and respond to the impacts of the PHE for COVID–19, understand the differences in measure specifications, train clinicians and office staff on a new reporting platform, and evaluate performance against the consolidated measure set to understand the impact this change will have on scoring standards. Comments included requests that implementation of the APP be delayed until 2022 or later; a voluntary transition period be offered to allow time for ACOs to adapt to the new requirements; a modified plan be implemented to allow ACOs to only report on a sample of patients while they prepare to implement automated population measurement; the first year following implementation of the APP be a pay-for-reporting year; exemptions to reporting requirements be offered; a bonus be offered to ACOs that are able to make the transition in 2021 without penalizing ACOs that need more time to prepare; and the timelines for implementing the APP and implementing the MIPS Value Pathways be aligned. One commenter requested that if the proposal is delayed until 2022 that CMS confirm the measure set that will be used starting in performance year 2022 in the CY 2021 PFS final rule so that ACOs have time to prepare. Commenters suggested that more stakeholder feedback should be collected before the proposed changes are finalized and that CMS should provide time for provider education, outreach, and support between finalizing a rule and implementing significant revisions to the quality reporting requirements.

Some commenters supported sunsetting the CMS Web Interface as a way to meet the CMS objective of increasing the utilization of CEHRT and digital quality measures or interoperability initiatives; but, many commenters had concerns about sunsetting the CMS Web Interface. Several commenters requested that sunsetting the CMS Web Interface should either be a gradual transition or be delayed to allow organizations to prepare for the transition to reporting under the APP and ease financial constraints practices are currently facing due to the PHE for COVID–19.

One commenter noted that even small changes to the program design could cause significant variance in performance for ACOs. The commenter recommended that CMS keep the current measure set, reporting mechanism, and scoring methods in place for performance 2021. Additionally, the commenter stated that healthcare providers should not be held accountable for performance against a benchmark that would not be set until the performance period closed and expressed concern that the PHE would continue to impact quality improvement efforts in 2021. The commenter recommended that CMS continue to monitor data submitted through the CMS Web Interface, evaluate the impact of the PHE for COVID–19 on quality performance, and revert all measures to pay-for-reporting or provide ACOs with the option to choose historical performance scores.

Other concerns raised by commenters included that the proposed APP does not align with the approach CMS uses to assess the quality of care furnished by other non-fee-for-service providers, such as Medicare Advantage organizations, even though the proposal would align quality scoring under the Shared Savings Program with MIPS. Two commenters noted that aligning requirements for Advanced APMs with MIPS program methodologies was a step backwards. One of these commenters stated that the guiding principle should be to ensure that there are strong incentives to participate in Advanced APMs relative to traditional Medicare fee-for-service, including being excluded from MIPS quality reporting processes, to increase the uptake of participation in Advanced APMs and decrease the need for MIPS over time. The other commenter stated that APMs should not have to align with MIPS, but rather MIPS reporting requirements should be structured to encourage clinicians to participate in APMs. Several commenters had concerns about changes to how ACO quality is reported, scored, and assessed and recommended that CMS obtain more stakeholder feedback before moving forward. One commenter expressed concern that the proposed APP does not support the Shared Savings Program's commitment to improved value, stating that the quality performance of ACOs should not be evaluated for purposes of the Shared Savings Program in the same manner as under other APMs or for individual MIPS clinicians because each APM has specific goals and objectives. Further, commenters noted that ACOs are distinct from single physician groups or hospital systems because ACOs are focused on managing population health and total cost of care for their aligned Medicare patient population, and therefore, should not be evaluated and assessed in the same manner as other types of healthcare providers. One commenter noted that the proposed APP will require significant investments while healthcare providers are still recovering from the PHE and this may disproportionately disadvantage smaller and rural ACOs and multi-practice independent physician ACOs operating many EHR systems.

Response: We thank commenters for their detailed feedback on the proposal to apply the APP to Shared Savings Program ACOs beginning in performance year 2021. We appreciate the support for our proposal, but also understand the concerns raised by a number of commenters about the proposed implementation of the APP for Shared Savings Program ACOs starting in performance year 2021. The primary concern expressed by commenters centered around the timeline for ACOs to implement appropriate infrastructure changes in order to be able to report under the APP beginning in performance year 2021, particularly given the PHE for COVID–19. Commenters also raised concerns about the proposed removal of the CMS Web Interface as a collection type. In addition, commenters were concerned about the proposed APP measure set, including use of measures based on all payer data. In light of the significant concerns raised by the commenters about implementing the APP for Shared Savings Program ACOs beginning in performance year 2021, we are modifying our proposal to apply the APP to determine the quality performance of Shared Savings Program ACOs as described below.

As discussed in section IV.A.3.c.1.c. of this final rule, we are extending the use of the CMS Web Interface as a collection type for the Quality Payment Program for CY 2021, and will sunset the CMS Web Interface starting with CY 2022. Accordingly, we are also modifying the quality measure set for the APP for Shared Savings Program ACOs to add the CMS Web Interface as an additional reporting option for performance year 2021, as discussed in this section and section IV.A.3.b. of this final rule. In addition, as discussed in

section III.G.1.c. of this final rule, we are modifying the proposed quality performance standard to include a gradual phase-in of the increase in the level of quality performance that would be required for ACOs to meet the quality performance standard under the APP for Shared Savings Program ACOs. We believe that these changes alleviate many of the concerns raised by commenters about the implementation of the APP for Shared Savings Program ACOs beginning in performance year 2021.

Therefore, we are finalizing, with modifications, our proposed revisions to the quality reporting requirements under the Shared Savings Program effective for performance year 2021 and subsequent performance years. These revisions will align the Shared Savings Program quality reporting requirements with the requirements that will apply under the APP under the Quality Payment Program as Shared Savings Program ACOs will be required to report quality data for purposes of the Shared Savings Program via the APP. Under this new approach, ACOs will only need to report one set of quality metrics via the APP that will satisfy the quality reporting requirements under both the Shared Savings Program and the MIPS. As discussed in the CY 2021 PFS proposed rule (85 FR 50231), there will not be separate quality reporting requirements under the Shared Savings Program as the quality measures reported for purposes of the APP will be used to determine the quality performance of the ACO for purposes of calculating shared savings and also shared losses, where applicable. The final APP quality measure set is listed in Tables 40 and 46 in this final rule. The policies finalized for the APP are discussed in section IV.A.3.b. of this final rule. In order to meet the quality reporting requirements under the Shared Savings Program, ACOs must meet the requirements described below and summarized in Table 39.

- For performance year 2021, ACOs will be required to report quality data via the APP, and can choose to actively report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate 2 measures using administrative claims data.

As noted in Tables 40 and 46 in this final rule three of the CMS Web Interface measures (Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134)) do not have benchmarks, and therefore, will not be scored. However, these measures are required to be reported in order to complete the CMS Web Interface dataset. Based on the ACO's chosen reporting option, either 6 or 10 measures will be included in the calculation of the ACO's quality performance score.

- For performance year 2022 and subsequent performance years, ACOs will be required to actively report quality data on the 3 eCQM/MIPS CQM measures via the APP. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate two measures using administrative claims data. All 6 measures will be included in the calculation of the ACO's quality performance score.

TABLE 39: Summary of final policies on applying the APP to Shared Savings Program ACOs beginning performance year 2021

	Performance Year (PY) 2021 (Reporting in CY 2022)	PY 2022 (Reporting in CY 2023)	PY 2023 (Reporting in CY 2024) and Subsequent PYs
Quality Reporting requirements	ACOs will be required to report the 10 measures under the CMS Web Interface **or** the 3 eCQM/MIPS CQM measures. ACOs will be required to field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. Based on the ACO's chosen reporting option, either 6 or 10* measures will be included in calculating the ACO's quality performance score.	ACOs will be required to actively report on the 3 eCQM/CQM MIPS measures and field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. All 6 measures will be included in calculating the ACO's quality performance score.	Same as PY2022
Quality Performance Standard	A quality performance score that is equivalent to or higher than the **30th** percentile across all MIPS Quality performance category scores. Quality performance standard met: ACOs are eligible to share in savings at the maximum sharing rate; ACOs in two-sided models share in losses based on their quality score or at a fixed percentage based on Track. Quality performance standard not met: ACOs are ineligible to share savings and owe the maximum amount of shared losses, if applicable.	Same as PY 2021 Shared savings and shared losses determinations same as PY2021	A quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores. Shared savings and shared losses determinations same as PY2021

* For performance year 2021, if ACOs choose to report via the CMS Web Interface, they will be required to report all 10 measures, but will be scored on only 7 of those measures.

The quality reporting requirements described above will provide ACOs with a one-year transition period during performance year 2021 where they will have the option either to continue to report via the CMS Web Interface or to report on the 3 eCQM/CQM MIPS measures before being required to report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022. As discussed in section III.G.1.c. of this final rule, we are also finalizing policies to phase-in the increase in the quality performance standard over 3 years. We believe that the phase-in policies, as summarized in Table 39, for applying the APP to Shared Savings Program ACOs address concerns raised by the commenters regarding the proposed timeline for implementing the APP and also help to mitigate the impact of the PHE for COVID–19 on ACOs. The phase-in policies provide ACOs with additional time to set up their systems and educate providers and office staff in order to report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022 and will also allow ACOs to become familiar with the new quality reporting requirements under the APP and gain experience reporting on the new measures before they are assessed under the higher quality performance standard beginning in performance year 2023. Commenters' concerns related to the APP quality measure set are addressed later in this section.

In the CY 2021 PFS proposed rule, we explained that the APP is designed to reduce reporting burden by enabling ACOs to track to a smaller set of measures under a unified scoring methodology. The policies we are adopting in this final rule are consistent with our goal of reducing reporting burden for ACOs. Under our final policies, the total number of measures will be reduced from 23 to either 6 or 13 measures (depending on the ACO's chosen reporting option) for performance year 2021 and to 6 measures beginning in performance year 2022.

For the commenter that expressed concern that providers should not be held accountable for performance against a benchmark that would not be set until the end of the performance period, we note that as discussed in section IV.A.3.d.1.b.ii. of this final rule, we are not finalizing the proposal to use performance period benchmarks and instead will continue to use historical benchmarks for quality measures for the CY 2021 MIPS performance period.

We stated in the CY 2021 PFS proposed rule (85 FR 50231) that, under the APP proposed in section III.C.3.b., eligible clinicians in Shared Savings Program ACOs would continue to receive full credit for the improvement activities performance category in 2021 based on their performance of activities required under § 425.112 of the Shared Savings Program regulations, as they do under current MIPS scoring policy. We also proposed that under the APP, the Promoting Interoperability performance category would be reported and scored by MIPS eligible clinicians and groups and calculated in the same manner described at § 414.1375. Shared Savings Program ACOs are not currently assessed on the MIPS Cost performance category as they are already subject to cost and utilization performance

assessments as part of the Shared Savings Program, and we proposed that the cost performance category would continue to be weighted at zero percent under the APP. Under the proposed APP, the four performance categories would be weighted as follows: Quality: 50 percent; Promoting Interoperability: 30 percent; Improvement Activities: 20 percent; and Cost: 0 percent. These policies are being finalized as proposed in section IV.A.3.b.4. of this final rule.

Under the APP, the quality performance score will be calculated for ACOs based on the same MIPS benchmarks that are used for other non-ACO group and individual reporters and reflect the method of data submission (for example, eCQM measures have benchmarks calculated using EHR data and CQM measures have benchmarks calculated using data for each specific non-EHR collection type). As discussed in section IV.A.3.d.1.b.ii of this final rule, we are not finalizing the proposal to use performance period benchmarks and instead will continue to use historical benchmarks for quality measures for the CY 2021 MIPS performance period. However, we note that, for the measures reported under the CMS Web Interface for performance year 2021, we will continue to use the Shared Savings Program benchmarks developed for the CMS Web Interface for performance year 2020. These Shared Savings Program benchmarks are based on data reported by ACOs, physicians, and groups through the CMS Web Interface, claims, and/or a registry from 2016, 2017, and 2018. The use of the Shared Savings Program benchmarks for the CMS Web Interface measures for performance year 2021 will allow us to be consistent with the approach currently used for scoring CMS Web Interface measures in the Shared Savings Program. We note that the Shared Savings Program benchmarks will also be used for the CMS Web Interface measures reported by groups and virtual groups under MIPS.

In the proposed CY 2021 PFS proposed rule (85 FR 50231 and 50232) we proposed that ACOs would be scored on the measures they report and will receive zero points for those measures they do not report. For example, if an ACO reported all three measures it is actively required to report but did not field a CAHPS for MIPS survey measure, the ACO would receive zero points for the CAHPS for MIPS survey measure, and that zero would be included in its MIPS Quality performance category score, along with its performance rates on the three measures it did actively report as well as the two claims-based measures included in the APP measure set. This proposed approach aligns with scoring under MIPS, rather than the current Shared Savings Program quality performance scoring methodology, which uses quality benchmarks established specifically for the Shared Savings Program and awards zero points for quality for ACOs that report some but not all of the required measures. We also noted that we believe this approach would be less punitive for ACOs than the current quality performance standard, under which ACOs that fail to completely report all quality measures receive a zero score for quality. We also noted that we believe that alignment with the MIPS scoring methodology would reduce the burden on ACOs of tracking to two different scoring methodologies. However, we proposed that if an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey the ACO would not meet the quality performance standard for purposes of the Shared Savings Program and would not be able to share in savings and would owe maximum shared losses, if applicable. We explained that if an ACO does not report any of the three measures it is required to actively report and does not field a CAHPS for MIPS survey, we did not believe that the remaining two claims-based measures in the APP core measure set would be sufficient to assess the quality of care provided by an ACO to its assigned beneficiaries and would likely not allow the ACO to achieve a MIPS Quality performance category score at or above the 40th percentile. Under our proposal, there would be no quality ''phase in'' for new ACOs or for newly introduced measures or for quality measures that undergo significant changes. All ACOs, regardless of performance year and agreement period, would be scored on all the measures in the APP for purposes of the Shared Savings Program quality performance standard.

We did not receive any comments on the proposal that if an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

Consistent with the quality reporting requirements finalized for Shared Savings Program ACOs under the APP, as discussed above, we are finalizing that:

- *For performance year 2021:* If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQM/MIPS CQM measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO would not meet the quality performance standard for purposes of the Shared Savings Program.
- *For performance year 2022 and subsequent performance years:* If an ACO does not report any of the three eCQM/MIPS CQM measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO would not meet the quality performance standard for purposes of the Shared Savings Program.

Comment: We received several comments related to the proposal to remove the pay-for-reporting year for ACOs in the first year of their first agreement period. Commenters expressed concern that new ACOs may require an initial performance year in the Shared Savings Program to build operations before they will be prepared to meet pay-for-performance standards. One commenter noted that new ACOs should have 1–2 years to learn the quality measures and plan improvement processes. Additionally, commenters expressed that removing the pay-for-reporting option for new ACOs would deter participation in the Shared Savings Program and negatively impact ACOs that are comprised of smaller physician practices and do not have hospital system support.

Response: We appreciate the commenters' concerns regarding the removal of the pay-for-reporting year for ACOs beginning an initial agreement period under the Shared Savings Program. The goal of the proposal was to align the Shared Savings Program quality performance standard with the APP under the Quality Payment Program, and there is no pay-for-reporting policy under the Quality Payment Program. However, in recognition of the concerns expressed by the commenters, we are modifying our original proposal and finalizing the following policy: Beginning January 1, 2022, for ACOs in the first performance year of their first agreement period under the Shared Savings Program, an ACO would meet the quality performance standard if it meets the MIPS data completeness and case minimum requirements on all three of the eCQM/MIPS CQM measures and fields the CAHPS for MIPS survey via the APP. The scoring policy under MIPS would be the same as for other ACOs.

We note that, as a result of CMS' decision to forgo an application cycle for a January 1, 2021 agreement start date in the Shared Savings Program, there will be no ACOs whose first

performance year of its first agreement period under the Shared Savings Program will begin on January 1, 2021. Therefore, this policy will be applicable for ACOs that are in the first performance year of their first agreement period in performance year 2022 or a subsequent performance year. We believe continuing this policy under the APP will provide new ACOs with additional time to set up their systems and educate providers and office staff, become familiar with the quality reporting requirements under the APP, and gain experience reporting on the measures under the APP before their performance is assessed in order to share in savings.

Comment: We received several comments related to the proposal to remove the pay-for-reporting year for newly introduced quality measures and quality measures that have undergone significant changes. Commenters suggested that a pay-for-reporting transition year ensures that quality measures that are new or have undergone significant changes do not have unintended consequences and allows potential issues with measure specifications to be identified before ACOs are held accountable for measure performance. Additionally, commenters suggested that a pay-for-reporting transition year would allow ACOs to adjust workflows and operations to ensure that quality data for the new or significantly changed measure is appropriately captured.

Response: We appreciate the commenters' concerns regarding the removal of the pay-for-reporting year under the Shared Savings Program for newly introduced quality measures and quality measures that undergo significant changes. We note that for each quality measure that an ACO submits that has significant changes, the total available measure achievement points are reduced by 10 points under the APP under current MIPS scoring policy (§ 414.1380(b)(1)(vii)(A)). We believe that adopting these policies for the Shared Savings Program is consistent with our goal to align the quality scoring methodology under the Shared Savings Program with MIPS. Therefore, we are finalizing our proposal to remove the pay-for-reporting year under the Shared Savings Program for newly introduced quality measures and quality measures that undergo significant changes.

In the CY 2021 PFS proposed rule (85 FR 50232), we stated that for MIPS scoring purposes, an ACO that fails to report via the APP would receive a zero in the Quality performance category under MIPS. If an ACO fails to report via the APP on behalf of its ACO participants then the ACO participants could report outside the ACO, on behalf of the MIPS eligible clinicians who bill through the TIN of the ACO participant and receive a MIPS Quality performance category score calculated at the ACO participant level. If ACO participants report outside the ACO via the APP, they would be eligible to earn full credit for improvement activities based on ACO participation. If ACO participants choose to report outside the ACO via a different MIPS reporting option, then regular MIPS scoring rules would apply (that is, eligibility to earn full credit for improvement activities and zero cost category weight would not be applied). We proposed in the CY 2021 PFS proposed rule (85 FR 50285) that MIPS eligible clinicians participating in ACOs also would have the option of reporting outside the APP, or within it at an individual or group level, for purposes of being scored under MIPS.

Comment: One commenter supported the proposal to allow reporting at the clinician, group practice, or ACO level for purposes of MIPS scoring as it would allow clinicians more flexibility and allow clinicians to be recognized for the work they are doing both inside and outside the context of the ACO. Other commenters expressed concerns regarding a policy under which individual clinicians and group TINs would have the option to report outside of the ACO for the purposes of MIPS scoring. The commenters expressed concerns that this approach would cause unnecessary confusion and instability and could fracture the foundation of the ACO by negating the commitment to the ACO. Similarly, one provider expressed concern that individual reporting adds a layer of complexity that is not conducive to ACO shared learnings and best practice identification. Additionally, commenters were concerned that this approach would not allow for a fair assessment of quality improvement efforts by clinicians or group practices participating in ACOs because certain organizations could select measures for which they have the highest historical performance. One commenter was concerned that reporting separately could disproportionately impact rural and smaller providers. The commenter recommended that CMS instead maintain the APM Scoring Standard approach for all ACO clinicians.

Another commenter had concerns that allowing TINs and/or NPIs to report data on their own, outside of the ACO, would cause even more confusion, citing previous concerns with the QPP help desk not understanding Medicare Shared Savings Program reporting requirements. Specifically, the commenter was concerned that ACO participant practices would think they do not need to report on the same measures that the ACO is required to report on under the Medicare Shared Savings Program.

Response: Policies related to eligible clinicians and groups reporting outside of the APP are discussed in detail in section IV.A.3.c.5 of this final rule. We note that the policy discussion above relates to ACO participants reporting outside of the ACO via the APP when the ACO fails to report data via the APP on behalf of its participant TINs. Eligible clinicians participating in an ACO may report to MIPS independently at the individual or TIN level. If ACO participants report outside the ACO via the APP, they will be eligible to earn full credit for improvement activities based on ACO participation and to have the cost performance category reweighted. However, if ACO participants report to MIPS according to traditional MIPS rules, as a group or individual MIPS eligible clinician, MIPS scoring rules apply. These policies are discussed in further detail in section IV.A.3.b. of this final rule. Additionally, we refer readers to section IV.A.3.e. of this final rule for information concerning our final policy on the hierarchy that will apply when more than one final score is associated with a TIN/NPI. We also refer readers to the discussion earlier in this section where we are finalizing our proposal that if an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

In the CY 2021 PFS proposed rule (85 FR 50232 and 50233), we proposed that for performance year 2021 and subsequent performance years, ACOs would be assessed on a smaller measure set under the APP for Shared Savings Program ACOs. The measures ACOs would be scored on would decrease from 23 measures to 6 measures and the number of measures on which ACOs would be required to actively report would be reduced from 10 to 3.

ACOs would report under the APP on the following 3 measures:

- Quality ID#: 001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%);
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure.

ACOs would report these measures via a submission method of their choice

that aligns with the MIPS data submission types for groups at § 414.1325(c) (direct, login and upload, or a third-party intermediary, described at § 414.1400, submitting on behalf of the ACO). ACOs would receive a score of between 3 to 10 points for each measure that meets the data completeness and case minimum requirements, which would be determined by comparing measure performance to established benchmarks. In addition, ACOs would need to field a CAHPS for MIPS survey and would be measured on two claims-based measures: The Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups; and the All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (MCC). Please see Table 36 in the CY 2021 PFS proposed rule (85 FR 50233) for full details on the measures proposed under the APP.

The measures proposed for inclusion in the measure set for the APP would align with the Meaningful Measures framework by identifying the highest priorities for quality measurement and improvement with the goals of reducing burden, promoting alignment, moving payment toward value, and identifying key quality performance metrics for consumers. The proposed measures would also encompass the meaningful measure domains of patient voice, wellness and prevention, seamless communication, chronic disease management, and behavioral health. We explained that we believe that the measures included in the APP are appropriate to assess the quality performance of Shared Savings Program ACOs as they focus on the management of chronic health conditions that are high priority and have high prevalence among the population of Medicare beneficiaries assigned to ACOs. We also noted that we believe that the measure set chosen for inclusion within the APP would move the quality measure set used in the Shared Savings Program toward a more outcome based, primary care focused measure set. In addition to creating a pathway that would reduce reporting burden for ACOs and allow their participating MIPS eligible clinicians to meet requirements under MIPS through a smaller measure set, requiring ACOs to report through the APP would also eliminate differences in the way ACOs are scored under the Shared Savings Program, as compared to the way their MIPS eligible clinicians are scored under MIPS.

We noted that under the current Shared Savings Program quality scoring methodology, the CAHPS for ACOs survey is counted as ten separate measures, while under the APP, the CAHPS for MIPS survey would be counted as one. We explained that we continue to value the patient voice and believe it should play a significant role in quality scoring. Using the CAHPS for MIPS survey would achieve that goal while further aligning the way in which the quality performance of ACOs and their MIPS eligible clinicians is scored under the Shared Savings Program and under MIPS, respectively. We noted that under the current Shared Savings quality scoring methodology, the 10 CAHPS for ACOs survey measures are scored as one domain, which makes up 25 percent of the Shared Savings Program quality score. In contrast, under the proposed approach, the CAHPS for MIPS survey would be counted as one measure out of the 6 measures that would be included in the calculation of the ACO's quality score under the APP. Both of these approaches have a similar weighting, which would maintain the relevance of patient voice. We also noted that we believed that the proposed approach under the APP of combining the CAHPS survey measures into a single measure for quality scoring purposes would allow Shared Savings Program ACOs to effectively target resources toward improving their assigned beneficiaries' experience of care in the areas for improvement on which they choose to focus, rather than having to track to ten separate survey measures, as is currently required by the CAHPS for ACOs used under the Shared Savings Program. We believed this approach would strike the right balance in reducing burden on ACOs and their participating providers and suppliers while preserving the patient's voice.

Shared Savings Program ACOs are currently required to report on a set of ten measures via the CMS Web Interface. While these measures were appropriate for use in the program in the past because they are primary care focused, we explained that we now recognize that the majority of the measures have highly clustered performance. This means that they cannot meaningfully distinguish quality performance across groups or ACOs. We also noted that we recognize the value in the use of primary care-focused measures and in that developing the proposed measure set for use under the APP, we had sought to preserve the measures we believed most reflect high priority quality measurement areas while also placing more emphasis on outcome-based claims measures, which minimize reporting burden and reflect greater opportunity for improvement.

We received many public comments on the proposed APP quality measure set as applied to Shared Savings Program quality performance scoring. The following is a summary of the comments we received and our responses. Please refer to section IV.A.3.b.(3)a. of this final rule for further discussion of comments and responses on the APP measure set.

Comment: Many commenters were supportive of the overall goal of simplifying reporting and aligning quality measurement approaches across federal programs. Several commenters were supportive of the reduction in the number of measures to reduce burden for healthcare providers, including the reporting burden placed on rural primary care practices. One commenter supported the proposed measure set, stating that it was adequate to address the chronic conditions among Medicare beneficiaries. One commenter indicated that the proposed reduced measure set focused on clinical outcomes and patient experience and is less burdensome for healthcare providers. One commenter supported this proposal and specifically stated that requiring former users of the CMS Web Interface to report all payer data will result in more patients receiving the benefit of services captured in the quality metrics, such as depression screening and pneumococcal vaccination status, rather than practices focusing those wellness measures solely on Medicare patients.

Response: We thank commenters for their positive feedback on the proposed APP quality measure set. The reduced measure set is intended to reduce reporting burden on ACOs and focus on quality measures that address patient outcomes and appreciate hearing that commenters also believe that the proposed measure set is consistent with those goals.

Comment: Several commenters were concerned that the proposed measure set is not appropriate for healthcare providers, such as ACOs, that are responsible for the total cost of care for the populations they serve and will not allow for robust assessment of clinical quality. Some commenters noted that the reduction in measures would significantly increase the impact of each measure on an ACO's overall quality score, which could risk over-emphasizing certain metrics and underlying patient conditions, as well as create more disruption when the measure set is revised. Additionally, several commenters were concerned that reducing the quality measure set would de-emphasize quality and would

not allow for a representative assessment of ACOs' quality improvement efforts, making it more difficult for ACOs to distinguish themselves based on the care they provide. One commenter was concerned that the reduction in measures would limit the ability for consumers to evaluate and compare the quality of providers. Another commenter had concerns that reducing the number of ACO quality measures would make specialists less likely to participate in the Shared Savings Program. Another commenter stated that the proposed measures are not relevant to ophthalmology specialty practices and suggested that the same measure sets used in MIPS be permitted for reporting through the APP or a protocol be put in place to determine if the measures are relevant to the clinicians reporting under the APP.

One commenter expressed concern that the narrower quality measure set would not appropriately protect patients because it would narrow the lens through which quality is assessed. Several commenters recommended that CMS work with stakeholders to refine the current set of measures to make it more appropriate for ACOs, which are responsible for total cost of care for the populations they serve. Another commenter stated that CMS should clarify if the outcome measures selected are representative of all of the different types of populations that ACOs treat and recommended that CMS take patient compliance and case mix into consideration when selecting measures because some patients may take longer to achieve health goals and ACOs may not have the same relative volume of patients with diagnoses such as diabetes and hypertension. One commenter suggested that CMS demonstrate that the proposed measures are of high significance to beneficiaries. Due to the impacts of the PHE for COVID–19, one commenter recommended that measures, such as breast cancer and colorectal cancer screening, be removed or treated as pay-for-reporting for performance year 2021.

Some commenters also expressed concern that the limited measure set would allow little room for random variation in one measure because random variation in one measure will have a larger impact when there are fewer measures to absorb the impact. One commenter stated that the limited measure set puts ACOs at a disadvantage compared to entities that are able to report outside of the APP and who can choose from larger pool of measures. Commenters also expressed concern that the reduction in the number of measures was too drastic and may have unforeseeable impacts on quality scoring for ACOs. One commenter suggested a more gradual, phased reduction where measures would be removed in rounds based on level of priority so that the impact of reducing the size of the measure set could be evaluated before additional measures are removed. Commenters also suggested that CMS monitor the smaller measure set to ensure the measures are not overly sensitive to minor changes in performance, random variation, or risk adjustment methodologies.

Other commenters suggested that CMS consider a broader measure set, and many commenters made recommendations for measures to be added to the measure set. One commenter suggested that a larger set of quality measures would be worth the additional burden because it would protect ACOs against errors in scoring, changes in risk adjustment methodology, and anomalies. Another commenter noted that while reducing the number of measures will reduce burden, ACOs also experience administrative burden due to year-to-year changes in the Shared Savings Program and the lack of alignment in measures between programs.

Response: We appreciate the commenters' concerns and recommendations regarding the narrower set of quality metrics that we proposed for the APP and its appropriateness for assessing the quality of care furnished by ACOs and their ACO participants. The transition to the APP measure set is intended to reduce reporting burden and eliminate differences in the way ACOs are scored compared to their MIPS eligible clinicians, while also moving toward a more outcome-based, primary care focused measure set. Additionally, we selected the measures to be included in the measure set because they are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program. These measures align with the Meaningful Measures framework while also being appropriate for assessing ACO quality performance as they focus on prevalent and high priority chronic health conditions. For example, hypertension and diabetes are chronic conditions that are applicable to both primary care practitioners and specialists.

Comment: Several commenters expressed concern that two of the six proposed quality measures (Measure # 479 Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups and Measure # TBD Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs) are focused on utilization even though the Shared Savings Program provides financial incentives for reducing avoidable hospital admissions and readmissions. Additionally, commenters stated that ACOs should be evaluated on quality measures that reflect core ACO competencies, such as care coordination activities and preventative health.

Response: Under the Shared Savings Program, an ACO that lowers growth in Medicare Parts A and B expenditures such that performance year expenditures for the ACO's assigned beneficiary population are below the ACO's updated historical benchmark by an amount that meets or exceeds the applicable minimum savings rate, may be eligible to share in savings. We do not believe that the incentive for ACOs to lower growth in expenditures, in order to generate shared savings, conflicts with assessment of the quality of care furnished by an ACO that includes measures of utilization, such as Measure # 479 Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups and Measure # TBD Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs. We note that section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization (such as rates of hospital admission for ambulatory sensitive conditions). Additionally, regarding the commenters' concerns about quality measures addressing core ACO competencies, we note that the APP measure set includes measures that address preventive health and care coordination. For example, the All-Cause Readmission (HWR) and All-Cause Unplanned Admissions for Multiple Chronic Condition measures fall into the Meaningful Measure domain of Promoting Effective Communication and Coordination of Care and the Preventive Care and Screening: Screening for Depression and Follow up plan falls into the Meaningful Measure domain of Promoting Effective Prevention & Treatment of Chronic Disease.

Comment: Several commenters expressed concerns about data collection methods in light of the increasing use of telehealth visits, as well as the various measure types (such as eCQM/MIPS CQM measures, CAHPS

for MIPS survey measures, and claims-based measures) used in the APP measure set. Commenters recommended that the measures selected be viewed through the lens of the current PHE environment and that all quality measures allow data to be collected during telehealth visits because many ACO participants have been relying on telehealth visits to continue seeing their patients during the PHE.

Response: We understand commenters' concerns related to the PHE for COVID–19. For the claims-based measures in the APP measure set, telehealth codes are not used to exclude claims from the measure calculation algorithm or the claims used to identify comorbidities as part of the risk adjustment model. Nine out of the ten CMS Web Interface measures, which are in the measure set for performance year 2021, allow the requirements for inclusion in the numerator to be met during a telehealth encounter. Quality ID#: 438 is the only measure that does not allow the quality action required to meet numerator compliance, to occur during a telehealth encounter. Similar to the Web Interface measures, the three eCQM/MIPS CQM measures in the APP measure set allow the requirements for inclusion in the numerator to be met during a telehealth encounter.

Comment: Commenters suggested that further consideration was needed to determine the appropriate composition of the quality measure set by measure type (that is, proportion of clinical, patient experience, and administrative claims measures) and the appropriate balance between clinical outcome measures and preventive care measures. One commenter recommended that, to the extent possible, CMS make use of administrative claims data, including CPT Category II codes, to determine measure performance with an opportunity for ACOs to provide supplementary data to reduce healthcare provider burden. One commenter supported the inclusion of eCQMs because eCQMs tie the use of technology to the Quality performance category by encouraging the proper use of EHRs and increase the reliability of data based upon not having human manipulation or intervention, but did not support the inclusion of administrative claims measures, citing concerns with reliability of the data and the cost to large practices.

Response: In response to comments on the appropriate composition of the quality measure set by measure type (that is, proportion of clinical, patient experience, and administrative claims measures) and the appropriate balance between clinical outcome measures and preventive care measures, we note that the APP measure set is intended to assess a sample of the areas where ACOs should be focused on improving the quality of care; it is expected that ACOs should be working to improve quality in additional areas as well. We appreciate the commenters' concerns regarding the use of administrative claims measures. Administrative claims measures have historically been used successfully to measure ACO quality performance under the Shared Savings Program. CMS calculates the administrative claims measures for ACOs, which minimizes the burden associated with these measures.

Comment: Commenters stated they would like to see more publicly available comparative data on ACO performance on the core quality measures under the Shared Savings Program, such as ACO–14, Influenza Immunization; ACO–19, Colorectal Cancer Screening; ACO–20, Breast Cancer Screening; and the previously used Pneumonia Vaccination measure. The commenters asserted that ACOs cannot be fairly assessed if they are only measured on the proposed APP measures because the measures do not reflect the true purpose of ACOs and the work they do in quality improvement.

Response: Each year when CMS releases the Shared Savings Program Financial and Quality reconciliation results, Public Use files (PUFs) are posted that provide the public with comparative data on the quality results for a given performance year. We note that data on the measures referenced by the commenters are publicly available in these PUF files. We disagree with commenters that ACOs cannot be fairly assessed if they are only measured on the measures in the APP measure set. As discussed above, we believe that the measures in the APP measure set are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program. These measures align with the Meaningful Measures framework while also being appropriate for assessing ACO quality performance as they focus on high prevalence, high cost, and high priority chronic health conditions.

Comment: Several commenters expressed concern that half of an ACO's quality score would depend on the CAHPS measure and two administrative claims measures. One commenter asserted that these measures have potential for unpredictability because minor differences in CAHPS scores can cause significant variation in ACOs' overall quality scores and there can be variance in scores on administrative claims measures related to risk adjustment changes. These commenters also expressed concern that CMS does not publish detailed measure specifications for the CAHPS or administrative claims measures. One commenter was concerned that the readmission measure would have a greater impact on the overall quality score under our proposed changes to the quality measure set because the commenter believes that the readmission measure is volatile.

Response: In regard to commenters' concern that the number of CAHPS measures is disproportionately high compared to clinical quality and outcomes measures, we note that under the new APP, the results of the CAHPS survey will account for a smaller proportion of ACOs' total quality score. Under the current scoring methodology, the CAHPS measures make up 1 domain or 25 percent of an ACO's quality score. Under the APP for Shared Savings Program ACOs that we are finalizing in this final rule, the results on the CAHPS measures will be combined to calculate a single composite score that will account for one sixth of the ACO's quality score or 16.7 percent or one tenth of the ACO's quality score or 10.0 percent, depending on which measure set the ACO reports on in 2021. Under both measure sets, patients' experience of care will meaningfully contribute to the overall quality score, while at the same time allowing other important measures of quality to also meaningfully contribute to the overall quality score.

Comment: Some commenters expressed concern that quality measures in the APP quality measure set have narrow performance ranges. One commenter suggested an alternative approach to calculating the benchmarks for quality measures that includes creating expanded percentiles due to concern that the current percentiles result in too narrow of a performance range where variation could be due to a small number of events or beneficiaries.

Response: We appreciate the commenter's recommendations regarding calculating benchmarks. We note that the seven CMS Web Interface measures with benchmarks for performance year 2020 are flat benchmarks that are used in accordance with § 425.502(b)(2)(ii) for measures that have clustered high performance rates. For the measures reported under the CMS Web Interface for performance year 2021, we will continue to use the Shared Savings Program benchmarks developed for the CMS Web Interface for performance year 2020.

We believe this practice addresses commenters' concerns about clustered performance having an adverse effect on ACOs' performance on the web interface measures. We refer readers to the MIPS benchmarking policy as defined at § 414.1380(b)(1)(ii), topped out measure scoring as defined at § 414.1380(b)(1)(iv), and flat percentage benchmark policy as defined at § 414.1380(b)(1)(ii)(C).

Comment: Several commenters suggested that CMS conduct further testing for risk adjustment of outcome measures, including social risk factors. These commenters requested CMS test the measures to ensure that minor changes to the risk adjustment methodology did not have significant impacts on the ACOs' quality scores. One commenter suggested that CMS enhance the risk adjustment of the outcome measures to address the high-risk patient populations of ACOs. Another commenter expressed concern that CMS should not include measures in the quality measure set used to assess ACO quality performance until they have been appropriately risk adjusted for sociodemographic factors, including socioeconomic status. The commenter explained that without appropriate risk adjustment for outcomes measures, such as the proposed readmission measure, the APP measure set could disproportionately impact the quality performance of ACOs that have an assigned beneficiary population served by ''essential hospitals''.

Response: Both of the proposed claims-based measures are risk-adjusted with beneficiary demographic characteristics and a wide range of clinical comorbidities to improve comparison of measure performance between organizations. These measures use a large number of Hierarchical Condition Category (HCC) comorbidity categories that account for many high-risk conditions among beneficiaries, which helps to adjust for differences in patient populations between ACOs. Risk adjusting in this manner is in accordance with best practices for risk adjustment to account for the higher level of risk for certain beneficiaries. We also note that the revised MCC measure has an additional risk adjustment not present in the original MCC measure that is in the current Shared Savings Program measure set. The revised measure adjusts for two area level social risk factors: (1) AHRQ socio-economic status (SES) index; and (2) specialist density. The original MCC measure does not contain any social risk factors in the risk adjustment.

We received several comments regarding the feasibility of using the alternative MIPS reporting options for purposes of quality reporting under the Shared Savings Program, which are summarized below.

Comment: Several commenters requested clarification of whether ACOs would report quality data for all patients regardless of attribution or payer status. Additionally, commenters explained that ACOs often operate using multiple EHR systems and requested clarification of whether ACOs would report separately for each EHR system. Several commenters expressed concern that using the alternative MIPS reporting options would result in ACOs being evaluated on the quality of the care furnished to all of the patients they serve. These commenters were concerned that this data would not be a true reflection of an ACO's quality improvement efforts and objected that it would not be fair to measure ACO quality based on non-attributed patients. Commenters also expressed concern that ACOs may not have the legal ability to access data for patients that are not attributed to the ACO, which may skew any assessment of quality. Additionally, one commenter noted that the differences between community health center populations and private practice populations would be magnified by the requirement to report on all patients served and that unlike the administrative claims measures that use HCC risk adjustment, the three clinical quality measures do not have similar adjustments. The commenter recommended that ''CMS use the same eligibility category definitions used in cost calculations for peer groups that can be assumed to carry forward to the entire patient population.'' The commenter also recommended that CMS further consider whether reporting for all patients will improve or worsen disparities and urged CMS to seek to incentivize improvement of disparities between patients served by community health centers and private practices through clinical quality and claims based measurement and benchmarking. Another commenter noted that current measure specifications would result in patients being eligible for measure denominators regardless of provider specialty designation and recommended that CMS incorporate logic into the measures to require a qualifying visit with a primary care provider. This commenter also recommended that CMS modify the reporting requirements for the eCQM/MIPS CQM measures to exclude patients who are not assigned to the ACO for purposes of reporting under the Medicare Shared Savings Program. The commenter explained that if reporting on the measures is not limited to the ACO's assigned beneficiary population, ACOs that include an Academic Medical Center (AMC) could be particularly negatively impacted because AMCs often care for patients who have primary care providers in other states and patients that are seen for short term destination services.

Some commenters expressed concern that vendors and developers would require additional lead time to update and test systems, configure tools and measurement algorithms to aggregate data at an ACO level, and handle the wave of new entities reporting using eCQMs/MIPS CQMs. Several commenters also noted that some ACOs would need to revise vendor participation agreements and contracts to allow them to access and report on data across all patients served by their ACO participants, which may cause further delays. Additionally, commenters also expressed concern that measure results may be unreliable due to vendors interpreting measure specifications differently.

Although some commenters acknowledged that ACOs would be reporting fewer quality metrics under the proposed APP, these commenters believe the proposal would increase reporting burden because ACOs would be required to report on a larger pool of patients and to become familiar with new data collection and reporting mechanisms. The commenters recommended that if we were to finalize the proposed eCQM/MIPS CQM measures, ACOs should be required to report on a sample population or a maximum of 50 percent of ACO beneficiaries. Alternatively, one commenter suggested that instead of ACOs being responsible for aggregating data for the eCQM/MIPS CQM measures included in the APP to create an ACO-wide score, CMS should be responsible for aggregating data on behalf of the ACO. The commenter stated that this process would reduce burden on the ACOs. Other commenters suggested that ACOs should only be required to report eCQMs for assigned beneficiaries while ACOs are transitioning away from the CMS Web Interface reporting mechanism and that CMS should work with industry leaders to create QRDA III aggregate TIN level reporting for assigned beneficiaries so that each ACO Participant TIN could submit the QRDA III file via the QPP website and CMS would calculate performance scores for the ACO. Additionally, commenters suggested that some ACOs may not have the time or financial capacity to explore other data collection and reporting mechanism workflows, especially due

to constraints caused by the PHE for COVID–19. For example, commenters explained that some ACOs would need to pay fees to modify EHRs, obtain new EHR interfaces and aggregation tools, update performance dashboards, and potentially work with a registry, and that these costs could pose a significant hardship for smaller ACOs.

Response: We acknowledge the concerns raised by the commenters about the change to reporting eCQMs/CQM MIPS measures, the need for time to transition to this new data collection format and collecting data on all-payer data and the time needed to set up new infrastructures for submitting this data to CMS. The CMS Quality Measurement Strategy is continuing to drive towards patient-centered, value-based care through the development, selection, and implementation of measurement that includes accelerating the move to digital measures, promoting the use of all payer data, increasing alignment of measures, and unleashing the voice of the patient through the use of patient reported outcomes. The APP measures include all-payer, patient-centric, and population-based outcome measures that are designed to promote the goals of the CMS Quality Measurement Strategy and align with the Meaningful Measures framework.

While the three eCQM/MIPS CQM measures are based on all payer data, we believe they are appropriate for assessing the quality of care furnished by the ACO as required by section 1899(b)(3) of the Act. These measures focus on the management of chronic health conditions that are a high priority and have high prevalence among Medicare beneficiaries. To the extent that these conditions are also prevalent among other populations of patients that receive services from the eligible clinicians participating in an ACO, we believe it is relevant to consider the quality of care that is furnished by ACO participants across all of their patients as part of assessing the overall quality of care furnished by the ACO. We also note that measuring care delivery to all patients is appropriate because improving care processes and practices is expected to improve care for all patients (for example, improvements to an electronic health record would be expected to improve care for all patients, not just Medicare patients). Additionally, CMS would not want ACOs participating in the Shared Savings Program to improve care for Medicare beneficiaries by reducing care quality for non-Medicare beneficiaries. Thus looking at the overall quality of care furnished to all patients is consistent with the goal of improving care furnished by ACOs by ensuring that care delivery is improving across all patients, rather than encouraging ACOs to focus disproportionately on improving measure performance for Medicare beneficiaries.

In addition, we believe the use of all-payer measures will provide an additional incentive for ACO participants to standardize care processes across all of their patient populations, which should improve the quality of care for all patients, including the ACO's assigned Medicare beneficiaries, while also making it easier to capture and report required data because ACOs would only need to capture and report one set of quality metrics to satisfy the reporting requirements under both MIPS and the Shared Savings Program.

With regard to concerns about reporting the three eCQM/CQM measures, ACOs will need to determine which collection type, either eCQM specifications captured via an EHR or MIPS CQM specifications intended to be used by groups or ACOs submitting measures via qualified registry, they will use to collect and report quality measure data. The ACO will report data in the aggregate on behalf of its ACO participants using the relevant measure specifications and could submit data via the following MIPS submission types using either direct login, such as application program interface or API, or sign in and upload. For example, the ACO could, on behalf of its ACO participants combine the results from all the ACO participant TIN QRDA 3 files, by adding numerators, denominators, etc. and create an aggregate QRDA3 file (or other compliant file format) and submit as an ACO to CMS. ACOs could also contract with a third party intermediary (such as a registry) to submit data on behalf of the ACO. We acknowledge commenters' concerns about the time needed to set up new infrastructures to report all-payer data; therefore, we are finalizing a phase-in approach to the quality reporting requirements under the Shared Savings Program. For performance year 2021, ACOs can opt to report 10 measures via the CMS Web Interface or the three eCQM/CQM measures as part of the APP. If an ACO opts to report via the CMS Web Interface, the requirements for which patients must be included for purposes of quality reporting would remain unchanged, ACOs would report on the provided beneficiary sample.

As discussed earlier in this section, in order to meet the quality reporting requirements under the Shared Savings Program and the MIPS, ACOs must meet the following requirements:

- For performance year 2021, ACOs will be required to report quality data via the APP, and an ACO can choose to actively report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate 2 measures using administrative claims data.
- For performance year 2022 and subsequent performance years, ACOs will be required to actively report quality data on the 3 eCQM/MIPS CQM measures via the APP. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate two measures using administrative claims data.

As discussed in section III.G.1.c. of this final rule, we are also finalizing policies to phase-in the increase in the quality performance standard over 3 years. We believe that the phase-in policies for applying the APP to Shared Savings Program ACOs and increasing the quality performance standard address the concerns raised by the commenters regarding the proposed timeline for implementing APP and the challenges of reporting on the measures in the APP measure set. The quality reporting requirements described above will provide ACOs with a one-year transition period during performance year 2021 in which they will have the option either to continue to report via the CMS Web Interface or to report on the 3 eCQM/CQM MIPS measures before being required to report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022. This transition period, coupled with the phase-in of the new quality performance standard discussed earlier in this section, will provide ACOs with additional time to set up their systems and educate providers and office staff in order to be prepared report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022 and will also allow ACOs to become familiar with the new quality reporting requirements under the APP and gain experience reporting on the new measures before they are assessed under the higher quality performance standard beginning in performance year 2023.

We received comments on the individual measures in the proposed measure set, which are summarized below.

Comment: We received several comments related to the proposal to include the CAHPS for MIPS measure in the APP for Shared Savings Program ACOs. One commenter noted support for the measures included in the CAHPS for MIPS. Several commenters

expressed concerns related to the CAHPS for MIPS measure. Specifically, the commenters noted that for this measure, small differences in quality can result in large quality score differences. The commenters stated that these differences are not meaningful and recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. Additionally, commenters were concerned that CMS has not detailed how the single composite CAHPS measure score will be calculated and were concerned with how the CAHPS measures are collected. Specifically, several commenters were concerned that the CAHPS measures use a small patient sample and rely on patients to recollect experiences that took place months before. One commenter had concerns about the small sample size for the CAHPS survey, citing previous experience with anomalies and unpredictable measure adjustments. Another commenter was concerned that the CAHPS sample size is the same for all ACOs regardless of ACO size; sampled patients do not represent the full population that ACOs serve; healthcare providers cannot provide supplemental information, such as more accurate contact information, in an effort to reach more patients; and surveys are only administered once annually with results received midway through the following performance year. Commenters recommended that CMS release additional information regarding how the CAHPS measure score will be calculated as soon as possible and recommended that CMS consider using a larger sample and modify the survey so that it is shorter and takes place closer in time to the care that beneficiaries are asked to assess.

Another commenter expressed concern that survey fatigue among patients was leading to declining survey response rates. The commenter recommended that CMS allow providers to use surveys already in place rather than requiring administration of an additional CAHPS for MIPS survey. Another commenter expressed concern over the subjective nature of the survey leading to significant variation in scores over time. Another commenter noted that the methodology of the CAHPS for MIPS and CAHPS for ACO surveys differ, with the CAHPS for MIPS survey having minimum survey size requirements as a function of the Taxpayer Identification Number (TIN) and the CAHPS for ACOs survey having minimum survey size requirements as a function of the ACO. The commenter requested that CMS be explicit if it intends to make any changes in the survey methodology with this proposal because shifting the survey size requirement to be based on TINs rather than the ACO as a whole will result in substantial financial burden to ACOs.

Response: We appreciate the commenters' concerns and recommendations regarding the CAHPS for MIPS measure. The CAHPS for MIPS survey uses the same survey instrument to assess the same patient experience domains as the CAHPS for ACO survey that is currently successfully used to measure ACO quality. The same shortened, streamlined version of the survey was implemented for both CAHPS for ACOs and CAHPS for MIPS in 2018, reflecting efforts by CMS to reduce the number of questions. We conducted analyses to assess the impact of aligning CAHPS scoring and benchmarking using 2019 CAHPS for ACOs and CAHPS for MIPS survey data. In 2019, the two programs used identical survey instruments. Analyses examined the impact of alignment on SSM scores, benchmarks, and quality points by comparing newly calculated SSM scores, benchmarks and quality points under the aligned approach to the official SSM scores, benchmarks, and quality points calculated under the original 2019 approach. The results of these analyses indicate that scoring ACOs using the MIPS methodology resulted in ACOs having a similar distribution of quality points as MIPS groups, which is wider than the distribution of quality points using the ACO scoring methodology. The wider score distribution is largely due to the differences across the two programs in the approach to benchmarking; CAHPS for ACOs uses flat percentage benchmarks for summary survey measures for which the 60th percentile of scores is greater than or equal to 80, or for which the 90th percentile of scores is greater than or equal to 95. CAHPS for MIPS does not use a flat percentage approach. While the shift away from flat percentage benchmarks may have the effect of creating larger differences in quality scores across Shared Savings Program ACOs, we believe that the scores will better reflect small differences in quality performance and will support the goal to improve the Shared Savings Program quality standard over time.

Beneficiaries assigned to an ACO or MIPS group, who are eligible for the CAHPS for MIPS or CAHPS for ACOs survey, are randomly selected for inclusion in the sample. Each ACO or MIPS group sample is therefore representative of the ACO or group population. Sample size requirements for both CAHPS for MIPS and CAHPS for ACOs were established using the results of analyses that sought to establish measures that allowed for meaningful comparisons to be made across ACOs and MIPS groups. Samples are drawn at the ACO level for CAHPS for ACOs, and at the MIPS group TIN level for groups. Target samples for all participating ACOs, groups, and virtual groups is 860; for ACOs, groups, and virtual groups with 860 or more survey-eligible patients, a random sample of 860 patients is drawn. In addition, groups and virtual groups with fewer than 860 survey-eligible patients are eligible to participate if they meet the following minimum sampling thresholds: Large groups or virtual groups with 100 or more eligible clinicians: 416 eligible patients; medium groups or virtual groups with 25–99 eligible clinicians: 255 eligible patients; and small groups or virtual groups with 2–24 eligible clinicians: 125 eligible patients. CMS will continue to draw the CAHPS survey samples for Shared Savings Program ACOs administering the CAHPS for MIPS survey at the Shared Savings Program ACO level, with a target sample size of 860 going forward.

Both surveys ask respondents to provide responses about their experiences of primary care during the previous 6 months. This look back period is used across many CAHPS survey efforts and enables a beneficiary to reflect on multiple care experiences with the focal provider named on the survey. While response rates have declined over time, the CAHPS for MIPS and CAHPS for ACOs surveys still reliably capture important information about the quality of care from patients' perspective, which are not captured via other data sources such as administrative claims data. We refer readers to section IV.A.3.b.3.a. of this final rule for additional details on the CAHPS for MIPS measure. With the alignment of CAHPS for ACOs with CAHPS for MIPS, the benchmarking and scoring methodology used for CAHPS for MIPS will be used. A single set of benchmarks will be calculated using data from all applicable CAHPS for MIPS reporters. The CAHPS for MIPS survey is scored as one quality measure, which is a different scoring approach from the current SSP quality scoring methodology that scores the ten CAHPS for ACOs summary survey measures in one patient/caregiver experience quality domain. As described in the CY 2017 Quality Payment Program final rule, each summary survey measure (SSM)

will have an individual benchmark and each SSM will be scored individually and compared against the benchmark to establish the number of points earned. The CAHPS score will be the average number of points across SSMs (81 FR 77284).

We received comments on the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure, which are summarized below.

Comment: Several commenters expressed concerns related to the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure. One commenter did not support this measure. Another commenter recommended that CMS consider NCQA's Plan All-Cause Readmission (PCR) measure instead because health plans use the PCR measure more widely as it is an NCQA accreditation requirement and the PCR measure is more robust and broader than the HWR measure because it includes patients 18 and older, while the HWR measure only includes patients 65 and older. Another commenter was concerned that the measure was sensitive to risk adjustment and has a narrow range, which negatively impacts ''community health center ACOs''. Another commenter noted that readmissions are low volume and can be influenced by factors outside the control of healthcare providers. Additionally, the commenter explained that an unintended consequence can occur when an ACO's base number of admissions is low compared to other ACOs with high numbers of admissions because it increases the sensitivity of this measure. This commenter suggested that CMS consider the Ambulatory Sensitive Condition Acute Composite measure instead. Other commenters noted that for this measure, small differences in performance can result in large quality score differences. The commenters stated that these differences in performance are not meaningful and recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. One commenter noted concerns about unintended consequences due to the measure not adequately considering the competing risk of mortality. This commenter suggested using an alternative measure, such as risk-adjusted home time.

Response: The proposed Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure is a re-specified version of NQF #1789 (Hospital-Wide All-Cause Unplanned Readmission Measure), and an adapted version of NQF #1789 that is currently being used successfully to assess ACO quality performance (ACO–8: Risk-standardized, All Condition Readmission (ACR)). We note that the MIPS HWR is clinically aligned to the ACO ACR measure, with the same cohort inclusion and exclusion criteria, outcome, measurement period, and risk adjustment variables, but the attribution and risk-standardized readmission rate calculation methodologies differ between the two measures. The ACO ACR measure attributes beneficiaries to ACOs prior to measurement, whereas the MIPS HWR measure is attributed to three clinician groups—primary inpatient provider, discharge clinician, and primary outpatient provider—based on measure specifications and care utilization data. In addition, the ACO ACR uses hierarchical logistic regression modeling to calculate risk adjustment while the MIPS HWR cannot use hierarchical logistic regression modeling because of attribution to multiple providers.

We believe that this re-specified version of NQF #1789 will provide a meaningful assessment of ACO quality performance. We will use the MIPS HWR three clinician group attribution method to attribute episodes at the ACO level. However, we will monitor and evaluate the ACOs' performance on the MIPS HWR measure to ensure compatibility including evaluating attribution at the ACO level, as well as refinements to risk adjustment and risk stratification and may revisit the decision to include this measure in the APP measure set for Shared Savings Program ACOs in future rulemaking. Both the MIPS HWR and ACO ACR measures will undergo the NQF endorsement/re-endorsement process during 2021, and we welcome stakeholder feedback on these measures.

We received comments on the three eCQM/CQM MIPS measures and the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs measure. These comments are summarized and responded to in section IV.A.3.B. of this final rule.

Table 40 lists the measures included in the final APP measure set.

TABLE 40: Measures included in the Final APM Performance Pathway Measure Set[1]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

[1] We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) do not have benchmarks and are therefore not scored; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2021 MIPS Performance year only.

In the CY 2021 PFS proposed rule (85 FR 50234), we noted that in addition to the measures included in the proposed APP measure set, based on recommendations from MedPAC in its 2015 Report to Congress: Medicare and the Health Care Delivery System,[56] we were considering adding a ''Days at Home'' measure that is currently under development, to the APP core measure set in future years, once it has been through the MAP pre-rulemaking process. We explained that any future additions to the measure set, including to add a ''Days at Home'' measure would be proposed and finalized through notice and comment rulemaking.

While CMS is not proposing to incorporate a ''Days at Home'' measure at this time, we received several public comments and recommendations about this measure. We greatly appreciate the commenters' views on a ''Days at Home'' measure, and we will take this feedback into consideration as this measure is developed and considered during future rulemaking cycles.

In addition, in the CY 2021 PFS proposed rule (85 FR 50234), we noted that we have received feedback from a few ACOs, including ACOs that have a significant number of beneficiaries in long-term care facilities or who are chronically ill or high-risk home bound

[56] *http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf.*

patients, that the measures ACOs are required to report are not always applicable to their patient population. Although we proposed to require ACOs to report via the APP, we also sought comment on an alternative approach that could be used in the event the three measures ACOs are required to actively report on are not applicable to their beneficiary population and there are more appropriate measure available under MIPS. Under this alternate approach, ACOs could opt out of the APP and report to MIPS as an APM entity. If the ACO decides to report as an APM entity to MIPS outside of the APP, CAHPS for MIPS would become optional; however, the ACO would be required to report PI and IA and would also be subject to cost under MIPS. In the event an ACO decides to report as an APM entity to MIPS outside the APP, we would use the ACO's MIPS Quality performance category score to determine if the ACO met the Shared Savings Program quality performance standard.

We sought comment on this alternative reporting approach for ACOs in the event the three measures ACOs are required to actively report are not applicable to their beneficiary population.

The following is a summary of the comments we received on this alternative approach and our response.

Comment: One commenter supported this approach as it would allow more flexibility for clinicians to be recognized for the work they are doing inside and outside the context of an ACO. A few commenters stated that they believed all three eCQM/MIPS CQM measures were applicable to all ACOs and expressed concerns that allowing some ACOs to report under this alternative approach would make program evaluation challenging and would not allow for a fair assessment of quality across ACOs because certain organizations would have the opportunity to select measures for which they have the highest historical performance.

Response: We appreciate the commenter's feedback on the alternate approach and CMS will consider the commenters' feedback as part of the development of any future policies in connection with this alternative approach.

c. Shared Savings Program Quality Performance Standard

The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions. We proposed to increase the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. As discussed in the CY 2021 PFS proposed rule (85 FR 50234), we explained that we believed the proposed changes would simplify the Shared Savings Program quality performance standard and were also consistent with the statutory requirement that we seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures or both (section 1899(b)(3)(C) of the Act). We proposed to increase the quality performance standard for all ACOs to achievement of a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We proposed to exclude entities/providers eligible for facility-based scoring from the overall MIPS quality score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS), which includes quality and cost.

Given that the statute requires that we seek to increase the quality performance standard over time, we explained our belief that changing the quality performance standard from the 30th percentile on one measure in each domain to a requirement that ACOs achieve a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, would be the next incremental step in increasing the quality performance standard. In the CY 2021 PFS proposed rule, we summarized the quality performance results for ACOs participating in the program in performance year 2018. Since the proposed rule was issued, we now have updated 2019 results. Under the current Shared Savings Program quality measurement methodology, 98.71 percent or 534 ACOs participating in the program in 2019 met the quality performance standard of complete and accurate reporting for ACOs in the first year of their first agreement period or the 30th percentile on one measure in each domain, for ACOs in their second or subsequent years of participation in the program. Of these ACOs, 497 were ACOs in second or subsequent years of participation in the program for which most quality measures were scored as pay-for-performance (P4P).

As discussed in the CY 2021 PFS proposed rule (85 FR 50234), eligible clinicians participating in Shared Savings Program ACOs who obtain QP status would continue to be exempt from MIPS, and therefore, would not be subject to MIPS payment adjustments. ACOs participating in a track (or payment model within a track) that is an Advanced APM may elect to report on behalf of their eligible clinicians who do not meet the threshold to earn QP status but do meet the lower payment or patient count threshold to achieve Partial QP status, and these Partial QPs would be subject to a MIPS payment adjustment. Conversely, if an ACO does not elect to report for the Partial QPs, they would not receive a MIPS score or payment adjustment and would have no reporting responsibilities for MIPS. We also explained that utilizing the MIPS Quality performance category scoring methodology to assess the quality performance for purposes of the Shared Savings Program of ACOs participating in tracks (or payment models within a track) that qualify as an Advanced APM would not change whether the eligible clinicians participating in the ACO obtain QP status and are excluded from MIPS, nor would it change the eligible clinicians' eligibility to receive Advanced APM incentive payments.

We received public comments on the proposal to revise the Shared Savings Program quality performance standard. The following is a summary of the comments we received and our responses.

Comment: We received several comments in support of increasing the quality performance standard to the 40th percentile of MIPS Quality performance category scores, all noting that the proposal aligned with CMS' goal of improving quality and reducing cost. We also received many comments opposing the overall approach of changing the quality performance standard to the 40th percentile of all MIPS Quality Performance Category Scores. Several commenters noted the potential uncertainty that ACOs would experience because they would not have a clear indication ahead of the performance year of what standards need to be met to be eligible to receive shared savings. Commenters suggested that CMS set a threshold for the number of measures that must meet the 40th percentile benchmark of at least 50 percent of all measures. Other commenters suggested that the quality performance standard should remain at the current level to allow more time for ACOs to familiarize the new reporting requirements under the APP. One commenter suggested that the MIPS scoring methodology is flawed and introducing a change in the quality performance standard now would cause

instability in the Shared Savings Program. One commenter expressed concerns over ACOs' abilities to meet thresholds on certain measures. One commenter noted that moving the quality performance standard to the 40th percentile would pose difficulties for organizations struggling with the readmission and unplanned admission for multiple chronic condition metrics. One commenter noted that the threshold change is drastic and also noted that with CAHPS data supplied only at the ACO level, not at the individual TIN level, it is hard to provide feedback to each participant TIN, and with ACOs trying to handle the current pandemic, it is difficult to influence performance in this area. In addition, several commenters expressed concerns over the potential impact of the pandemic and other natural disasters on quality performance and the uncertainty ACOs could face and suggested the implementation of a new quality performance standard should be delayed. Commenters expressed concern over the limited time to gain familiarity with the new requirements and difficulty meeting this new quality performance standard for certain measures. Several commenters expressed concerns regarding the shift from a domain-based scoring approach to the proposed approach of requiring an ACO to achieve an overall quality score equivalent to the 40th percentile of all MIPS quality performance category scores. One commenter expressed concerns that such a scoring approach would have major financial implications for the sustainability of the Shared Savings Program as financial implications for ACOs are much higher than MIPS participants.

Response: We appreciate the commenters' feedback on our proposal to revise the Shared Savings Program quality performance standard. In light of the concerns raised by the commenters, we are finalizing a modified version of our original proposal to allow for a gradual phase-in of the increase in the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. Specifically, we are finalizing that an ACO would meet the quality performance standard if:

- For performance years 2021 and 2022, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores; and
- For performance year 2023 and subsequent performance years, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

Achieving the applicable quality performance standard for a performance year will enable the ACO to share in the maximum amount of savings based on their Track, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions for that performance year.

These policies are summarized in Table 39 in this final rule. The impact on shared savings payments as a result of these final policies is described in section VIII.H.7.a. of this final rule. We are also finalizing our proposal to exclude entities/providers eligible for facility-based scoring from the determination of the overall MIPS Quality performance category score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS), which includes quality and cost.

We believe that this phase-in of the quality performance standard, coupled with our decision to phase-in the reporting requirements under the APP for Shared Savings Program ACOs, as described in section III.G.1.b.(1). of this final rule, will alleviate many of the concerns raised by the commenters, especially those related to the PHE for COVID–19 and other natural disasters in 2020. We will monitor ACO performance under the new quality reporting requirements to determine the impact of this measured increase to the quality performance standard and may revisit this policy in future rulemaking if necessary to promote an attainable quality performance standard and degree of improvement. With respect to the concerns raised by commenters regarding the limited time to gain familiarity with the new requirements, the phase-in policies will give ACOs additional time to set up their systems to report all payer data on the three eCQM/MIPS CQM measures under the APP. The phase-in will also allow ACOs additional time to become familiar with the new quality reporting requirements and gain experience reporting on the new measures under the APP before they are assessed under the increased quality performance standard beginning in performance year 2023. We note that the quality performance standard that we are adopting for performance years 2021 and 2022 is analogous to the current quality performance standard, under which ACOs are required to achieve the 30th percentile on one measure in each domain. Therefore, we believe that this approach to phasing in the new, higher quality performance standard is consistent with the statutory requirement in section 1899(b)(3)(C) of the Act that we seek to increase the quality of care furnished by ACOs over time. We also note that ACOs will not be required to meet the 30th or 40th percentile (depending on the performance year) for all measures reported under the APP in order to meet the quality performance standard. If an ACO performs poorly on one measure under the APP, the ACO may still be able to meet the quality performance standard based on its performance across the remainder of the measures set. For commenters that expressed concern that ACOs would not have an indication prior to the start of the performance year of what standards would need to be met to be eligible to receive shared savings, we note that, as discussed in section IV.A.3.d.(1)b.ii. of this final rule, we are not finalizing the proposal to use performance period year benchmarks and instead will continue to use historical benchmarks for quality measures for the CY 2021 MIPS performance period.

Comment: We received several comments related to how the quality performance standard would be assessed and applied. One commenter expressed uncertainty about whether CMS would assess the quality performance standard based on the aggregate score on all quality measures or require a 40th percentile score on each individual measure. Other commenters noted that they were uncertain if the quality performance standard was meant to apply across all domains in the aggregate, or across each individual domain at the 40th percentile.

Response: Under the phase-in we are adopting in this final rule, an ACO's quality performance score must be equivalent to or higher than the 30th or 40th percentile (depending on the performance year) across all MIPS Quality performance category scores in order to meet the quality performance standard. ACOs will not be required to achieve a performance score that is equivalent to or higher than the 30th or the 40th percentile (depending on the performance year) on each individual measure in order to meet the quality performance standard. We are also clarifying that each ACO's quality performance score will be calculated using the ACO's performance on the measures reported under the APP, any applicable MIPS bonus points, and quality improvement points. Please refer to section IV.A.3.b. of this final rule for information on scoring under the APP. Unlike the scoring methodology currently used in the Shared Savings Program, there are no quality domains

under the APP; rather, each measure will be weighted equally.

In the CY 2021 PFS proposed rule (85 FR 50234 and 50235), we proposed to specify in a new section of the Shared Savings Program regulations at § 425.510, policies governing the application of the APP to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021. As proposed, this new section would include a general provision specifying that CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements, and meets all other applicable requirements, the ACO is eligible to receive shared savings. We proposed that this general provision would also indicate that CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the proposed new section, we also specified the requirement that ACOs must report quality data via the APP established under § 414.1367 according to the method of submission established by CMS, and that CMS retains the right to audit and validate quality data reported by an ACO according to § 414.1390.

We did not receive any public comments on the proposed regulation at § 425.510. We are finalizing § 425.510 as proposed.

We also proposed to specify in a new section of the Shared Savings Program regulations at § 425.512 provisions for determining the ACO quality performance standard for performance years beginning on or after January 1, 2021. We proposed to specify that the quality performance standard is the overall standard the ACO must meet in order to be eligible to receive shared savings for a performance year, and that an ACO will not qualify to share in savings in any year it fails to meet the quality performance standard. Further, we proposed to specify that for all ACOs, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. In addition, we proposed to specify that if an ACO does not report any of the three measures ACOs are actively required to report and does not field a CAHPS survey, the ACO would not meet the quality performance standard.

We did not receive any public comments on the proposed regulation at § 425.512. However, as a result of our decision to modify our original proposal to provide for a phase-in of the new quality reporting requirements under the APP for Shared Savings Program ACOs, as described in section III.G.1.b.1. of this final rule, and the increase in the quality performance standard, as described earlier in this section, we are finalizing the proposed regulations at § 425.512 with modifications, as described below.

Revising § 425.512(a)(3) to provide that:

- For performance years 2021 and 2022. CMS designates the quality performance standard for all ACOs, with the exception of ACOs in the first performance year of their first agreement period, as the ACO reporting quality data via the APP established under § 414.1367, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.
- For performance year 2021. If an ACO does not report any of the ten CMS Web Interface measures or any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.
- For performance year 2022. If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP the ACO will not meet the quality performance standard.

Adding a new provision at § 425.512(a)(4) to provide that for performance years 2023 and subsequent performances:

- CMS designates the quality performance standard for all ACOs, with the exception of ACOs in the first performance year of their first agreement period, as the ACO reporting quality data via the APP established under § 414.1367, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.
- If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP the ACO will not meet the quality performance standard.

We are also revising § 425.512 to add a new language at § 425.512(a)(2) to provide that for performance year 2022 and subsequent performance years, for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO meets the data completeness requirement at § 414.1340 and case minimum requirement at § 414.1380 on the three measures it is actively required to report and fields a CAHPS for MIPS survey via the APP, the ACO will meet the quality performance standard. Finally, we are also revising the references to MIPS Quality performance category scores in § 425.512(a)(3) and (4) to make clear that entities/providers eligible for facility-based scoring are excluded.

In addition, we proposed to modify the existing Shared Savings Program regulation at § 425.508, on incorporating quality reporting requirements related to the Quality Payment Program. We proposed to add a provision applicable to 2021 and subsequent performance years, which would specify that ACOs must submit quality data via the APP established under § 414.1367 to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category. We also proposed related technical and conforming modifications to § 425.508.

We did not receive any public comments on the proposed modifications, and related technical and conforming modifications to § 425.508. We are finalizing all of the modifications to § 425.508 as proposed.

d. Use of ACO Quality Performance in Determining Shared Savings and Shared Losses

In section III.G.1.d of the CY 2021 PFS proposed rule (85 FR 50235 and 50236), we proposed modifications to the Shared Savings Program regulations on the use of the ACO quality performance in determining shared savings and shared losses. We explained that section 1899(d)(1)(A) of the Act specifies an ACO is eligible to receive a shared savings payment for a portion of the savings generated for Medicare, provided that the ACO meets both the quality performance standards established by the Secretary and achieves the required level of savings against its historical benchmark. Section 1899(d)(2) of the Act provides the authority for the actual payments for shared savings under the Shared Savings Program. Specifically, if an ACO meets the quality performance standards established by the Secretary (according to section 1899(b)(3) of the

Act), and meets the savings requirements, a percent (as determined appropriate by the Secretary) of the difference between the estimated average per capita Medicare expenditures in the year, adjusted for beneficiary characteristics, and the benchmark for the ACO, may be paid to the ACO as shared savings and the remainder of the difference shall be retained by the Medicare program. The Secretary is required to establish limits on the total amount of shared savings paid to an ACO. We have also incorporated performance-based risk in the form of shared losses into certain financial models using the authority under section 1899(i)(3) of the Act to use other payment models.

The Shared Savings Program's one-sided shared savings only models, and two-sided shared savings and shared losses models are specified in subpart G of the Shared Savings Program regulations. For agreement periods beginning on July 1, 2019, and in subsequent years, eligible ACOs may participate under either: (1) The BASIC track, which includes a glide path consisting of five levels (Levels A through E) that allows eligible ACOs to begin under a one-sided model (Level A or Level B) and incrementally phases-in higher levels of risk and potential reward (Levels C, D, or E) (§ 425.605); or (2) the ENHANCED track, a two-sided model with the highest level of risk and potential reward (§ 425.610). Further, according to the May 8th COVID–19 IFC (85 FR 27574 and 27575), ACOs that entered a first or second agreement period with a start date of January 1, 2018, whose participation agreements expire December 31, 2020, may elect to extend their agreement period for an optional fourth performance year, spanning January 1, 2021, to December 31, 2021. This includes ACOs that entered agreement periods under Track 1 (a one-sided model), Track 2 (a two-sided model), and Track 3 (subsequently renamed the ENHANCED track). Further, this option to elect a 12-month extension of the agreement period also applies to ACOs participating in the Track 1+ Model whose participation agreements expire December 31, 2020.

Under the Shared Savings Program regulations, for both one-sided models and two-sided models, CMS uses the ACO's quality performance to determine the ACO's eligibility to receive shared savings, and the rate at which ACOs share in these savings. We base the final shared savings rate on the ACO's quality performance. For ACOs meeting the quality performance standard, the final shared savings rate is equal to the product of the ACO's quality score and the maximum sharing rate. The maximum sharing rate is specific to the ACO's track/level of participation as follows: 50 percent for ACOs participating in Track 1;[57] 60 percent for ACOs participating in Track 2;[58] 40 percent for ACOs participating in Level A or Level B of the BASIC track;[59] 50 percent for ACOs participating in Levels C, D, or E of the BASIC track;[60] and 75 percent for ACOs participating in the ENHANCED track.[61] The upside of the Track 1+ Model is based on Shared Savings Program Track 1; therefore, a maximum sharing rate of 50 percent applies to Track 1+ Model ACOs.[62]

Depending on the track, the ACO's quality performance may also be used to determine the amount of the ACO's shared losses, for ACOs under two-sided models. ACOs participating in the Track 1+ Model, and Level C, D, or E of the BASIC track are subject to a fixed shared loss rate (also referred to as the loss sharing rate) of 30 percent regardless of quality performance.[63] Under Track 2 and the ENHANCED track, the shared loss rate is calculated as one minus the ACO's final shared savings rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively, and the shared loss rate may not be less than 40 percent for both tracks.[64] For ENHANCED track ACOs, this 40 percent minimum shared loss rate is expressly stated in the current regulations, whereas for Track 2 ACOs, it is the implicit minimum shared loss rate as calculated based on the inverse of the maximum final shared savings rate for the track. Track 2 and ENHANCED track ACOs that do not meet the quality performance standard for the performance year will be accountable for shared losses based on the highest shared loss rate for their track.

In light of the proposed changes to the Shared Savings Program's quality performance standard, in the CY 2021 PFS proposed rule, we also proposed modifications to the regulations that specify the circumstances under which an ACO will qualify for a shared savings payment based on its quality performance and the determination of the rate at which the ACO will share in savings based on its quality performance.

For all tracks, we proposed to specify, in revisions to the regulations, the requirements that must be met for an ACO to qualify for a shared savings payment for performance years beginning on or after January 1, 2021. We proposed that to qualify for shared savings, an ACO must meet the minimum savings rate requirements established for the track/level, meet the proposed quality performance standard described in section III.G.1.c. of the proposed rule, and otherwise maintain its eligibility to participate in the Shared Savings Program under part 425. We proposed to revise §§ 425.604(c) (Track 1), 425.605(c) (BASIC track), 425.606(c) (Track 2), and 425.610(c) (ENHANCED track) to reflect these requirements.

We also proposed revisions to the provisions establishing the final sharing rate for all tracks. We proposed that for performance years beginning on or after January 1, 2021, if an ACO that is otherwise eligible to share in savings meets the proposed quality performance standard as described in section III.G.1.c. of the proposed rule, the ACO will share in savings at the maximum sharing rate according to the applicable financial model, up to the performance payment limit. We proposed that if the ACO fails to meet the proposed quality performance standard, the ACO would be ineligible to share in savings. We proposed to specify these policies in revisions to the provisions governing Track 1 (§ 425.604(d)), the BASIC track (§ 425.605(d)(1)(i)(A) (Level A), (d)(1)(ii)(A) (Level B), (d)(1)(iii)(A) (Level C), (d)(1)(iv)(A) (Level D), (d)(1)(v)(A) (Level E)), Track 2 (§ 425.606(d)), and the ENHANCED track (§ 425.610(d)).

We also proposed modifications to the methodology for determining shared losses under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, to account for the proposed revisions to the quality performance standard. If the ACO meets the quality performance standard, we proposed to determine the shared loss rate as follows:

- *Step 1:* Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.
- *Step 2:* Calculate the product of the quotient described in step 1 and the

[57] Refer to § 425.604(d).

[58] Refer to § 425.606(d).

[59] Refer to § 425.605(d)(1)(i)(A), (d)(1)(ii)(A).

[60] Refer to § 425.605(d)(1)(iii)(A), (d)(1)(iv)(A), (d)(1)(v)(A).

[61] Refer to § 425.610(d).

[62] Refer to the Track 1+ Model Participation Agreement, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

[63] Provisions specifying the shared loss rate for two-sided models of the BASIC track are specified in § 425.605(d)(1)(iii)(C), (d)(1)(iv)(C), (d)(1)(v)(C). The shared loss rate applicable to Track 1+ Model ACOs is specified in the Track 1+ Model Participation Agreement.

[64] Refer to §§ 425.606(f), 425.610(f).

sharing rate for the relevant track, either 60 percent for Track 2 or 75 percent for the ENHANCED track.

• *Step 3:* Calculate the shared loss rate as 1 minus the product determined in step 2. Consistent with the existing structure of the financial models: Under Track 2, the shared loss rate may not exceed 60 percent, and may not be less than 40 percent; under the ENHANCED track, the shared loss rate may not exceed 75 percent, and may not be less than 40 percent.

Under the proposed approach, for an ACO that meets the quality performance standard we would take into consideration the ACO's quality score when determining the ACO's share of losses. An ACO with a higher quality score would owe a lower amount of losses compared to an ACO with an equivalent amount of losses but a lower quality score, so long as the ACO's quality score results in a shared loss rate within the range between the minimum shared loss rate (40 percent) and the maximum shared loss rate (60 percent under Track 2, or 75 percent under the ENHANCED track). To the extent the ACO's quality score results in a shared loss rate outside these limits, the shared loss rate is set to the minimum or maximum rate (as applicable). We also proposed to revise the regulation at § 425.606(f) to expressly state both the minimum and maximum shared loss rates for Track 2.

In addition, we also proposed that if the ACO fails to meet the quality performance standard, the shared loss rate would be 60 percent under Track 2 or 75 percent under the ENHANCED track. We explained that we believed this approach would maintain symmetry with the proposed approach to determining shared savings under Track 2 and the ENHANCED track based on quality performance. Thus, an ACO that fails to meet the quality performance standard would be ineligible to share in savings and would owe the maximum amount of shared losses.

We proposed to specify these provisions for determining the shared loss rate under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, through modifications to the regulations at §§ 425.606(f) and 425.610(f). We also proposed technical and conforming changes to these provisions for clarity, and to specify that the current policy would continue to apply for purposes of determining the shared loss rate for Track 2 ACOs and ENHANCED track ACOs for performance years (or a performance period) beginning on or before January 1, 2020.

We received public comments on the proposed use of ACO quality performance in determining shared savings and shared losses. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for the proposed approach to determining the rate at which ACOs will share in savings based on quality performance, for performance years beginning on or after January 1, 2021. A few commenters expressed support for eliminating the sliding scale for determining shared savings based on quality performance, and allowing ACOs to earn savings at the maximum sharing rate according to the applicable financial model if the quality performance standard is met. One commenter expressed support for making an ACO ineligible to share in savings if it fails to meet the quality performance standard.

Several commenters explained that they supported the proposed approach because it provides a larger reward to ACOs for meeting CMS' increased quality performance standard. One commenter explained the proposed approach would simplify financial calculations.

Some commenters opposed the proposed approach to determining whether an ACO shares in savings at the maximum rate, or not at all, based on whether or not the ACO meets the proposed revised quality performance standard. Commenters suggested instead that CMS use a scoring approach that is more similar to the current domain-based scoring approach rather than an all-or-nothing approach as proposed. In particular, some commenters preferred an approach that differentiates higher quality performers and rewards quality improvement over time with a higher savings percentage.

Some commenters urged CMS to better reward high quality performers, as is done in the Medicare Advantage program by providing bonuses or higher shared savings rates to high quality performers or those that notably improve quality scores over time.

Some commenters suggested that the proposed approach would make it more challenging for ACOs to share in savings, and that may discourage program participation by ACOs. One commenter explained that the change from a quality multiplier on payment, to all-or-nothing savings, adds another significant dimension of risk to the program for ACOs that depend on shared savings to operate. A few commenters expressed concern that the proposed approach may limit participation by ACOs that depend on shared savings to support their participation in the Shared Savings Program, such as to cover ongoing operational costs and infrastructure costs. One commenter suggested that this dynamic could ultimately discourage participation by physician-led ACOs or lead to consolidation of physician-led ACOs with larger entities to manage the ACO, ultimately stifling innovation.

Several commenters expressed concern about an approach that makes the ACO's ability to share in savings an all-or-nothing proposition, particularly as CMS also proposed to increase the quality performance standard for ACOs. One commenter expressed concerns about the proposed approach, suggesting it places the entirety of an ACO's shared savings payment at risk if one measure is missed. This commenter explained that an all-or-nothing approach to determining an ACO's eligibility to share in savings, in combination with higher standards and volatile measures, would negatively impact their decision about continuing their participation in the Shared Savings Program, including whether to enter into a new participation agreement under the Shared Savings Program or take on increased downside risk, and their overall investment in the program.

One commenter supported raising the quality performance standard and allowing ACOs that meet that standard to receive full shared savings, provided that this change accompanies a smaller program measure set and the standard is assessed as an average of the measures. The commenter noted that it would not support a 40th percentile standard applied to each measure given its concerns about several of the measures.

Response: We agree with the comments suggesting that the proposed approach will simplify program calculations going forward. Under the proposed approach, an ACO is eligible to share in the maximum amount of savings if it meets the quality performance standard, and is ineligible to share in savings if it fails to meet the quality performance standard, thereby removing the variation in sharing rates based on the ACO's quality performance score.

We believe a number of factors mitigate commenters' concerns about the determination of shared savings based on the revised quality performance standard for the Shared Savings Program. As discussed elsewhere in section III.G.1 of this final rule, in response to commenters' concerns about the transition to the APP

for Shared Savings Program ACOs, we are finalizing our proposal with certain modifications, including to allow for continued use of the Web Interface as a reporting mechanism for PY 2021, and to allow for a more gradual phase-in of the quality performance standard. We believe this phase-in will give ACOs additional time to prepare to transition to the APP, and thereby to prepare to meet the new quality reporting requirements and quality performance standard, and in turn to meet the requirements for sharing in savings. Further, under the APP (as described in section III.G.1.c of this final rule), we will determine whether the ACO has met the quality performance standard based on the ACO's quality performance score as compared to the relevant percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, that comprises the quality performance standard for the applicable performance year. Therefore, an ACO that performs poorly on one or several measures under the APP may still have the opportunity to share in savings at the maximum sharing rate, if it meets the quality performance standard based on its performance across the remainder of the measure set.

Additionally, we note that while our final policy will require ACOs to meet a higher quality performance standard starting in PY 2023, ACOs that achieve the quality performance standard maximize their upside potential. In contrast, under the existing approach, which is designed to differentiate between higher and lower quality performers, it is rare for ACOs to achieve the maximum sharing rate based on quality performance under the program's pay for performance standards that phase-in after the ACO's first performance year in the Shared Savings Program. Under the existing approach, in an ACO's first performance year in the program, the ACO will receive a quality score of 100 percent, and therefore the maximum sharing rate based on quality performance, if it completely and accurately reports all quality measures. For subsequent performance years, under a pay for performance standard, we multiply an ACO's quality score (as a percentage) by the maximum sharing rate for the track in which the ACO participates to determine the ACO's final sharing rate based on quality performance. Thus, ACOs are effectively limited from maximizing their upside potential since their quality scores are typically below 100 percent. We believe that allowing ACOs to maximize their upside potential year after year, as provided under the policies we are finalizing in this rule, could further facilitate ACOs' participation in the Shared Savings Program and their investments in accountable care activities to meet the program's goals.

We appreciate commenters' concerns that this revised methodology for measuring quality performance and rewarding ACOs with savings based on their quality performance could have the effect of limiting participation by certain types of ACOs. However, we believe commenters' concerns are mitigated by the aforementioned factors, including the gradual phase-in of the quality performance standard and the potential for ACOs to more consistently share savings at the highest sharing rates under the revised approach. We anticipate monitoring to determine if the revised quality performance standard and the approach of determining an ACO's eligibility to share in savings at the maximum sharing rate based on their ability to meet the quality performance standard, disproportionately disadvantage certain ACOs based on composition and experience in the Shared Savings Program, among other factors, and will consider whether any adjustments may be warranted. Any changes to the policies we are adopting in this final rule would be made through notice and comment rulemaking.

In response to commenters' preference that CMS retain an approach that continues to reward quality improvement over time, we note that under the APP, the MIPS quality improvement scoring methodology, as specified under § 414.1370(g)(1)(iv), will be used in determining an ACO's quality performance score. Under this approach, we will consider the improvement in an ACO's quality performance category achievement percent score from the previous performance period in the determination of whether the ACO has met the quality performance standard, and therefore whether the ACO is eligible for sharing savings at the maximum sharing rate. In comparison, the Shared Savings Program's current quality improvement reward as specified in § 425.502(e)(4) rewards ACOs that demonstrate quality improvement with a higher quality score, and therefore a potentially greater share of savings, but the amount of shared savings still would not exceed the maximum sharing rate. Accordingly, given that quality improvement will be factored into determining an ACO's quality performance score under the APP and ACOs that meet the quality performance standard will be eligible to share in savings at the maximum sharing rate for their track, we do not believe it is necessary to provide any additional adjustment to shared savings for ACOs that demonstrate improved quality performance over time.

Further, at this time, we decline commenters' suggestions that we adopt an approach for rewarding higher quality performance, and quality improvement, similar to the approach specified under Medicare Advantage. We note that the focus of the proposed changes was on aligning the Shared Savings Program's quality performance standard with the APP under the Quality Payment Program (as previously described elsewhere in section III.G.1 of this final rule). Further, we believe the approach we are finalizing will be effective in rewarding ACOs that perform well on quality measures and improve quality performance over time. As we have previously described, ACOs that meet the revised quality performance standard, which phases-in a higher performance standard over time, are eligible to share in savings at the maximum sharing rate, and we will factor quality improvement into determining an ACO's quality performance score under the APP.

After considering the comments and the modifications that we are making to phase-in the new quality reporting requirements and quality performance standard under the APP, we are finalizing as proposed our approach to determining an ACO's eligibility for shared savings based on quality performance, for performance years beginning on or after January 1, 2021.

Comment: The few commenters that discussed the proposed approach to determining shared losses based on quality performance were generally supportive of the proposed approach. In particular, commenters expressed support for the proposed approach under which an ACO's shared losses are based on its quality performance such that an ACO with a higher quality score would owe lower shared losses. One commenter supported the proposed modifications to the shared loss calculations for Track 2 and the ENHANCED track, which would still allow an ACO's quality score to be taken into consideration as long as the loss rate stays within the minimum and maximum range, because they would simplify financial calculations.

Response: We are finalizing as proposed the modifications to the methodology for determining shared losses under Track 2 and the ENHANCED track for performance years beginning on or after January 1, 2021, to

account for the revisions to the quality performance standard discussed elsewhere in this section III.G.1 of this final rule.

We did not receive comments on the revisions we proposed to make to the regulations to specify the requirements that must be met for an ACO to qualify for a shared savings payment for performance years beginning on or after January 1, 2021. We are finalizing as proposed the revisions to §§ 425.604(c) (Track 1), 425.605(c) (BASIC track), 425.606(c) (Track 2), and 425.610(c) (ENHANCED track) to reflect these requirements. Specifically, to qualify for shared savings, an ACO must meet the minimum savings rate requirements established for the track/level, meet the quality performance standard established under the new provision at § 425.512 as described in section III.G.1.c. of this final rule, and otherwise maintain its eligibility to participate in the Shared Savings Program under part 425.

After considering the public comments we received, we are finalizing as proposed revisions to the provisions establishing the final sharing rate for all tracks. For performance years beginning on or after January 1, 2021, if an ACO that is otherwise eligible to share in savings meets the quality performance standard established under § 425.512, the ACO will share in savings at the maximum sharing rate according to the applicable financial model, up to the performance payment limit. If the ACO fails to meet the quality performance standard, the ACO will be ineligible to share in savings. These final policies are specified in revisions to the provisions governing Track 1 (§ 425.604(d)), the BASIC track (§ 425.605(d)(1)(i)(A) (Level A), (d)(1)(ii)(A) (Level B), (d)(1)(iii)(A) (Level C), (d)(1)(iv)(A) (Level D), (d)(1)(v)(A) (Level E)), Track 2 (§ 425.606(d)), and the ENHANCED track (§ 425.610(d)).

After considering the public comments we received, we are also finalizing our proposals for determining the shared loss rate under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, through modifications to the regulations at §§ 425.606(f) and 425.610(f). Specifically, we will determine the shared loss rate as follows:

- *Step 1:* Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.
- *Step 2:* Calculate the product of the quotient described in step 1 and the sharing rate for the relevant track, either 60 percent for Track 2 or 75 percent for the ENHANCED track.
- *Step 3:* Calculate the shared loss rate as 1 minus the product determined in step 2. Consistent with the existing structure of the financial models: Under Track 2, the shared loss rate may not exceed 60 percent, and may not be less than 40 percent; under the ENHANCED track, the shared loss rate may not exceed 75 percent, and may not be less than 40 percent. If the ACO fails to meet the quality performance standard, the shared loss rate will be 60 percent under Track 2 or 75 percent under the ENHANCED track.

We received no comments on our proposed technical and conforming changes to §§ 425.606(f) and 425.610(f), for clarity. We are finalizing these changes as proposed in order to specify the policy that would apply for purposes of determining the shared loss rate for Track 2 ACOs and ENHANCED track ACOs for performance years (or a performance period) beginning on or before January 1, 2020. We are also finalizing our proposed revision to § 425.606(f) to expressly state both the minimum and maximum shared loss rates for Track 2.

e. Compliance With the Quality Performance Standard

(1) Background

As discussed in more detail in section III.G.1.c. of the CY 2021 PFS proposed rule (85 FR 50234), the quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions. Section 1899(d)(4) of the Act authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. Through earlier rulemaking we established an approach to enforce ACO compliance with the quality performance standards, as specified in the Shared Savings Program regulations at § 425.316 (see 76 FR 67951, 80 FR 32818 and 32819, 81 FR 80492 through 80494).

To identify ACOs that do not meet the established quality performance standards, we review the ACO's quality data submission. Under our current policies, as specified in § 425.316(c), if an ACO does not meet quality performance standards or fails to report on one or more quality measures, in addition to actions set forth at §§ 425.216 and 425.218, we will take the following actions:

- The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a corrective action plan (CAP). CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.
- The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standards in the following year, the agreement will be terminated.
- An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

Further, according to § 425.224(b), in evaluating the eligibility of a renewing ACO or re-entering ACO to enter a new participation agreement with CMS for participation in the Shared Savings Program, we consider the ACO's history of noncompliance with the program's quality performance standard. For evaluating ACOs that entered into a participation agreement for a 3-year period, we consider whether the ACO failed to meet the quality performance standard during 1 of the first 2 performance years of the previous agreement period. For evaluating ACOs that entered into a participation agreement for a period longer than 3 years, we consider whether the ACO failed to meet the quality performance standard for 2 consecutive performance years and was terminated as specified in § 425.316(c)(2), or whether the ACO failed to meet the quality performance standard for 2 or more performance years of the previous agreement period, regardless of whether the years were consecutive.

The terms ''renewing ACO'' and ''re-entering ACO'' are defined in the regulations at § 425.20. We define renewing ACO to mean an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either: (1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or (2) an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program. We define

re-entering ACO to mean an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions: (1) Is the same legal entity as an ACO that previously participated in the program and is applying to participate in the program after a break in participation, because the ACO's participation agreement expired without having been renewed, or the ACO's participation agreement was terminated under § 425.218 or § 425.220; or (2) is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

(2) Revisions

In the CY 2021 PFS proposed rule (85 FR 50237), we explained that we had revisited the provisions of § 425.316(c) on monitoring compliance with quality reporting and performance requirements in light of our proposed modifications to the quality performance standard. We proposed to modify the introductory text at § 425.316(c) to state that we will review an ACO's submission of quality measurement data to identify ACOs that are not meeting the applicable quality performance standard under § 425.500 or § 425.512. As proposed, we would retain the discretion to request additional documentation from an ACO, ACO participants, or ACO providers/suppliers. Further, we noted our belief that in conjunction with the proposed changes to the quality performance standard, it would be appropriate to strengthen our policies for compliance with the quality performance standard by broadening the conditions under which CMS may terminate an ACO's participation agreement when the ACO demonstrates a pattern of failure to meet the quality performance standard.

As currently structured, the regulation at § 425.316 does not specify what actions CMS will take when an ACO fails to meet the quality performance standard for multiple, nonconsecutive performance years, or 2 consecutive performance years that span 2 agreement periods (that is, the last performance year of an agreement period and the first performance year of the subsequent agreement period). Accordingly, we proposed a new approach that CMS would follow to monitor for and address an ACO's continued noncompliance with the applicable quality performance standard for performance years beginning on or after January 1, 2021. Noncompliance with the quality performance standard during earlier performance years would continue to be subject to the rules set forth at § 425.316(c)(1) through (3), which we proposed would be consolidated at § 425.316(c)(1). For performance years beginning on or after January 1, 2021, we proposed that when CMS determines an ACO fails to meet the quality performance standard (as described in section III.G.1.c. of the proposed rule), CMS may take the actions prior to termination set forth at § 425.216, and may terminate the ACO's participation agreement according to § 425.218. In addition to the actions set forth at §§ 425.216 and 425.218, we proposed to adopt a specific approach that CMS would follow to monitor for and address an ACO's continued noncompliance with the quality performance standard.

We proposed that ACOs exhibiting a pattern of failure to meet the quality performance standard would be terminated from the program. Specifically, we proposed to terminate an ACO's participation agreement when the ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period or fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order. We also proposed that we would terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period. In addition, we proposed that we would terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period. We proposed to amend § 425.316(c)(2) to reflect this new approach.

We explained that the proposal to terminate an ACO if it fails to meet the quality performance standard for 2 consecutive performance years within an agreement period would be consistent with the current approach. However, we also proposed to terminate an ACO's participation agreement if the ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether these years are in consecutive order. In the December 2018 final rule (83 FR 67831), we extended participation agreements from 3-years to 5-years. ACOs participating under a 5-year agreement period may show a pattern of failure to meet the quality performance standard in performance years that are not consecutive. Therefore, we noted that we believe it is important to continue to monitor ACOs throughout their 5-year agreement period and if an ACO fails to meet the quality performance standard for 3 nonconsecutive performance years we proposed to terminate their participation agreement.

Additionally, we noted that we were concerned that a renewing ACO's quality performance results for the last performance year of the current agreement period would not be available for us to consider in reviewing the ACO's application to renew its agreement, as currently provided in § 425.224(b)(1)(ii)(A). We noted that we had a similar concern with respect to some re-entering ACOs (particularly, an ACO that notifies CMS of its decision to terminate its participation agreement and subsequently submits an application to re-enter the program for the next start date following the effective date of its termination). To prevent these ACOs from remaining in the program, despite a pattern of noncompliance with the quality performance standard, we proposed that if we determine that the last performance year of the ACO's previous agreement period was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the prior agreement period, CMS would terminate the ACO's new participation agreement. For example, if an ACO failed to meet the quality performance standard in the first, third and fifth performance years of a 5-year agreement period, or failed to meet the quality performance standard in the fourth and fifth performance years of a 5-year agreement period, results for the fifth performance year would not be available until after the ACO has renewed and entered a new agreement period. We explained that, in both examples, we would anticipate determining during the first performance year of the ACO's new agreement period that the ACO had failed to meet the quality performance standard for the last performance year of

its previous agreement period. Therefore, under the proposal, CMS would terminate the ACO's new participation agreement during the first performance year of that agreement period.

Furthermore, we expressed concern that an ACO could have a pattern of failing to meet the quality performance standard for consecutive years spanning 2 agreement periods. Therefore, if a renewing or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods (the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period), we proposed to terminate the ACO's participation agreement. We noted that we anticipated that quality performance results for the ACO's first performance year of its new agreement period would be available during the second performance year of the ACO's new agreement period. Therefore, CMS would terminate the ACO's new participation agreement during the second performance year of the new agreement period.

We recognized there would be additional complexity in the application of these policies to a new ACO that is identified as a re-entering ACO because of its ACO participants' prior participation in another Shared Savings Program ACO. Under the proposed approach, we would apply to the re-entering ACO the other ACO's quality performance for previous years (prior to the start of the re-entering ACO's agreement period) and would terminate the re-entering ACO if the other ACO is determined to have failed to meet the quality performance standard in 2 consecutive performance years within an agreement period, or if the other ACO is determined to have failed to meet the quality performance standard for 3 performance years (in nonconsecutive order) within an agreement period. We acknowledged that under the proposed approach, this could occur in circumstances when the other ACO's most recent performance year of failed quality performance is determined after the start of the new, re-entering ACO's agreement period. Further, under the proposed approach, we would also consider whether the other ACO failed to meet the quality performance standard in the most recent performance year prior to the start of the new, re-entering ACO's agreement period, and whether the new, re-entering ACO also fails to meet the quality performance standard for its first performance year. Under our proposal, because these 2 performance years of failed quality performance would be consecutive, we would terminate the participation of the new, re-entering ACO.

We noted that because a significant percentage of the ACO participants in the new, re-entering ACO were previously participating in this other ACO, we believed it would be appropriate to hold the new, re-entering ACO accountable for the quality performance of the other ACO. According to the definition of re-entering ACO, more than 50 percent of the entity's ACO participants must have participated together in the same ACO within a 5-performance year lookback period. As a result, over half of the new, re-entering ACO's ACO participants can be considered to have contributed to the failed quality performance of this other ACO. We explained that if we were to disregard the recent failed quality performance of this other ACO, these ACO participants would be allowed to continue participation in the Shared Savings Program as part of the new, re-entering ACO, and potentially take advantage of program flexibilities, despite a pattern of noncompliance with the quality performance standard.

We proposed to implement these policies starting with performance year 2021 and subsequent years. We acknowledged that an ACO currently participating under a performance agreement spanning 5-years could fail the quality performance standard for a performance year starting in 2019 under § 425.502. The same ACO could then again fail the quality performance standard under the proposed new provision at § 425.512 in performance years 2021 and 2023. In this scenario, the ACO would have failed the quality performance standards for 3 nonconsecutive years under the same agreement period, but the ACO would not be terminated in this scenario because the proposed policies would apply starting with performance year 2021. However, we noted that if the ACO decides to apply as a renewing or re-entering ACO, we would review its history of noncompliance with the requirements of the Shared Savings Program as provided under § 425.224(b)(1) when determining whether to approve its application.

We also explained that under the current regulation at § 425.316(c)(3), an ACO will not qualify to share in savings in any year in which it fails to report accurately, completely, and timely on the quality performance measures. Consistent with the proposed revisions to the quality performance standard under the Shared Savings Program discussed in section III.G.1.c. of the proposed rule, we proposed to specify in the proposed new provision at § 425.512 that, for performance years beginning on or after January 1, 2021, an ACO will not qualify to share in savings in any year it fails to meet the quality performance standard.

We noted that the termination of an ACO's participation agreement for failure to meet the quality performance standard under the proposed approach described in the proposed rule, would also make the ACO subject to the payment consequences of early termination as specified in § 425.221(b). Under § 425.221(b)(1)(ii), if the participation agreement is terminated at any time by CMS under § 425.218, the ACO is not eligible to receive shared savings for the performance year during which the termination becomes effective. Under § 425.221(b)(2)(ii)(B), an ACO participating under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. These policies would apply whenever an ACO is terminated for non-compliance with the quality performance standard in accordance with § 425.316(c).

We proposed to revise § 425.316(c) to incorporate the proposed approach for monitoring ACO compliance with the quality performance standard for performance years beginning on or after January 1, 2021. We also proposed to make other technical and conforming changes to the regulations at § 425.316(c). In particular, we proposed to amend the existing provisions for monitoring ACO compliance with the quality performance standards to specify that those provisions are applicable to performance years (or a performance period) beginning on or before January 1, 2020.

We noted that we also continue to believe in the importance of considering an ACO's history of noncompliance with the quality performance standard in evaluating the eligibility of a renewing ACO or a re-entering ACO to enter a new agreement period under the Shared Savings Program. In light of our proposed changes to § 425.316(c), we proposed to make conforming changes to § 425.224(b)(1)(ii)(A), which authorizes CMS to approve or deny a renewing ACO's or re-entering ACO's application to participate in the Shared Savings Program based on an evaluation of the ACO's history of non-compliance with the quality performance standard. Specifically, we proposed to revise § 425.224(b)(1)(ii)(A) to state that as part

of its evaluation of a renewing or re-entering ACO's history of noncompliance with the requirements of the Shared Savings Program, we will evaluate whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

We received public comments on the proposals concerning monitoring compliance with the quality performance standard. The following is a summary of the comments we received and our responses.

Comment: We received a few comments supporting our proposals to modify our policies for monitoring ACOs for compliance with the quality performance standard. Two commenters suggested we modify the proposed approach to provide that an ACO's participation agreement will be terminated after 3 consecutive years of failing to meet the quality performance standard. One commenter noted this approach would align with policies used in Medicare Advantage where plans' contracts may be terminated after three consecutive years of failing to achieve an overall quality rating of at least 3 stars. One of the commenters further suggested we terminate an ACO's participation agreement for failure to meet the quality performance standard after 4 non-consecutive years of failing to meet the quality performance standard.

Response: We appreciate the additional suggestions for modifying our approach for monitoring and enforcing compliance with the quality performance standard. Since the beginning of the Shared Savings Program, we have terminated 3 ACOs for failure to report quality for two consecutive years. We decline to modify the proposed changes to our policies for monitoring compliance with the quality performance standard to provide for termination only after 3 consecutive years or 4 non-consecutive years of noncompliance. We believe the policies as proposed, under which an ACO will be terminated following 2 consecutive years or 3 non-consecutive years of non-compliance, provide ACOs enough time to implement processes and procedures that will allow them to meet the quality performance standard. If an ACO repeatedly fails to meet the quality performance standard the ACO should not continue participating in the Shared Savings Program. The Shared Savings Program seeks to both improve quality performance and reward high quality, while reducing the growth in Medicare spending. We believe these requirements for enforcing compliance with the quality performance standard help to hold ACOs accountable for the quality of the care they furnish to their beneficiaries and further encourage ACOs to demonstrate consistently that they are providing high quality of care to their beneficiary populations year over year.

Comment: We received a few comments opposing our proposed policies for terminating an ACO's participation agreement for a pattern of failure to meet the quality performance standard. One commenter suggested we develop a compliance standard that includes educating ACOs and issuing corrective action plans. The commenter suggested that we should terminate an ACO's participation agreement only if the ACO's failure to meet the quality performance standard was due to ''gross negligence.''

Response: We appreciate the commenter's suggestions; however, we note that we already incorporate education and outreach activities and compliance activities into our management and operations of the Shared Savings Program. We encourage and support ACOs in sharing their best practices and lessons learned from their experiences participating in the Shared Savings Program. We have hosted in-person learning collaboratives where ACOs can meet one another and listen to case study presentations about their experiences. We have also hosted webinars where ACOs present case studies on providing value-based care, including sharing lessons learned and best practices in quality reporting. Recordings of these webinars and supporting materials remain available for ACOs participating in the Shared Savings Program to access. Additionally, as proposed, if the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216, which may include requesting a corrective action plan from the ACO. Lastly, we disagree with the commenter's suggestion that CMS should not terminate an ACO's participation agreement unless the ACO's failure to meet the quality performance standard was due to ''gross negligence.'' Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. The gross negligence standard advocated by the commenter would set far too high a bar for enforcement of the quality performance requirements and thereby do little to encourage improvement in quality of care over time. We believe it is important for ACOs to meet the quality performance standard and that ACOs that repeatedly fail to meet the quality performance standard should not be able to continue their participation in the program.

We did not receive comments concerning our proposal to make conforming changes to § 425.224(b)(1)(ii)(A). After considering the comments received, we are finalizing our proposed policies without modifications. We are revising § 425.316(c) to modify our approach for monitoring ACO compliance with the quality performance standard for performance years beginning on or after January 1, 2021. We are also making technical and conforming changes to amend the existing provisions on monitoring ACO compliance with the quality performance standards to specify that those provisions are applicable to performance years (or a performance period) beginning on or before January 1, 2020. Lastly, we are making conforming changes to § 425.224(b)(1)(ii)(A) to provide that as part of evaluating a renewing or re-entering ACO's application to participate in the Shared Savings Program, CMS will consider whether the ACO has demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

f. Updating the Process Used To Validate ACO Quality Data Reporting

In the CY 2017 PFS final rule, we finalized modifications to the quality measures validation audit process. These modifications changed the overall audit process from a 3-phased medical record review to an audit conducted in a single phase. Under our current process, if selected for an audit, an ACO must provide beneficiary medical records data to substantiate the quality data reported by the ACO. As part of the audit, CMS calculates an overall audit match rate, which is derived by dividing the total number of audited records that match the information reported in the CMS Web Interface by the total number of the medical records audited. For example: (1) If the ACO has an audit match rate of 90 percent or above it will pass the audit; (2) if the ACO has an audit match rate of less than 90 percent, but greater than 80 percent, the ACO may be required to submit a CAP under § 425.216 for CMS approval; (3) if the ACO has an audit match rate of less than 80 percent, absent unusual circumstances, we will adjust the ACO's

overall quality score proportional to the ACO's audit match rate, which may have implications for the ACO's financial reconciliation.

We stated in the CY 2021 PFS proposed rule (85 FR 50239) that under our proposal to align the quality reporting requirements under the Shared Savings Program with quality reporting under the APP, we believed it would be appropriate to also align with the MIPS Data Validation and Audit (DVA) process (§ 414.1390). Rather than continuing to validate ACO quality data reporting under the Shared Savings Program, we noted that we believed it would be more appropriate for MIPS to validate the data submitted by ACOs for the three measures in the APP, as ACOs will be able to select the submission method for these measures and the MIPS DVA is based on submission method. We also noted that we believed streamlining the approach to data validation and audit would minimize administrative burden associated with the audit for ACOs as they would only need to track to one validation process, and for ACOs in a track (or payment model within a track) that does not meet the definition of an Advanced APM, the results of the audit would be applicable for purposes of both the Shared Savings Program and MIPS.

We proposed to address the audit and validation of data used to determine the ACO's quality performance in a new provision we proposed to add to the Shared Savings Program regulations at § 425.510(c). Specifically, we proposed that CMS would retain the right to audit and validate the quality data reported by an ACO under § 425.510(b) according to § 414.1390.

We received public comments on the proposed updates to the process used to validate ACO quality data reporting. The following is a summary of the comments we received and our response.

Comment: We received comments that supported our proposal. One commenter indicated that the proposed approach would allow for the continued oversight of quality performance, while reducing administrative burden on ACOs as they ensure audit readiness.

Response: We are finalizing the updates to the process used to validate ACO quality data reporting and the conforming changes to § 425.510(c) as proposed. Specifically, we are finalizing that CMS retains the right to audit and validate quality data reported by an ACO via the APP according to the MIPS DVA process for performance years beginning on or after January 1, 2021. We believe that this updated process will reduce administrative burden on ACOs by allowing them to track only one validation process that will be applicable for both the Shared Savings Program and MIPS. We note that in section III.G.1.e. of this final rule, we are finalizing our proposals related to ACOs' compliance with the quality performance standard, including the proposed approach to terminating ACOs that exhibit a pattern of failure to meet the quality performance standard.

g. Changes to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2021 and Subsequent Performance Years

As discussed in section III.G.1.c. of the CY 2021 PFS proposed rule, we proposed to make changes to the quality performance standard for the Shared Savings Program for the performance year beginning on January 1, 2021, and subsequent performance years. We explained that we continue to believe it is appropriate to adjust the quality performance scores for ACOs affected by extreme and uncontrollable circumstances. Therefore, we proposed to update the extreme and uncontrollable circumstances policy under the Shared Savings Program consistent with the proposal to align the quality reporting requirements for the Shared Savings Program with the proposed APP. Specifically, for performance year (PY) 2021 and subsequent performance years, we proposed to set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, to equal the 40th percentile MIPS Quality performance category score. If the ACO is able to report quality data and meet the MIPS data completeness and case minimum requirements, we would use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we would apply the 40th percentile MIPS Quality performance category score. We noted that we believed this approach would be appropriate as it aligns with the proposed threshold for meeting the quality performance standard allowing impacted ACOs to share in savings at their maximum sharing rate. We acknowledged that using the 40th percentile may not offer the same level of protection for ACOs incurring losses that would receive the higher of their ACO quality score or the mean ACO score under the current policy. However, we noted that for ACOs in Track 2 and the ENHANCED track, under which shared losses are determined based in part on an ACO's quality performance, ACOs are also afforded relief from shared losses through the application of the extreme and uncontrollable circumstances policy under which shared losses are reduced based on the percentage of the year and percentage of assigned beneficiaries impacted by an extreme and uncontrollable circumstance.

In the CY 2021 PFS proposed rule (85 FR 50240), we explained that under the proposed revisions to the quality reporting requirements, we would no longer generate a CMS Web Interface quality reporting sample for ACOs because ACOs would no longer be reporting measures via the Web Interface; therefore, we proposed to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries, rather than the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which is currently used. We explained that using the quarter four list of assigned beneficiaries would be an appropriate alternative because the file is generated after the end of the fourth quarter and would offer a more complete representation of the population of assigned beneficiaries that reside in an area that is impacted by an extreme and uncontrollable circumstance during the performance year. Accordingly, we solicited comment on our proposed revisions to the extreme and uncontrollable circumstances policy for performance year 2021 and subsequent performance years.

We proposed to specify our proposed policies for addressing the effect of extreme and uncontrollable circumstances on ACO quality performance for performance year 2021 and subsequent performance years in the proposed new provision at § 425.512. In addition, we proposed to include policies that parallel the existing policies, as specified in § 425.502(f), for determining when an extreme and uncontrollable circumstance has occurred and identifying affected ACOs. In particular, we proposed to include a provision, similar to the current provision at § 425.502(f)(1), to establish our policies for determining whether an ACO has been affected by an extreme and uncontrollable circumstance. We also

proposed to include a provision, similar to the provision at § 425.502(f)(2), to establish the policies that would apply for calculating an affected ACO's quality performance score. Similar to the existing provision at § 425.502(f)(3), we proposed to specify that we would apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred, and the affected areas. Consistent with the existing policy under § 425.502(f)(4), this new provision would also specify that we have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

We received public comments on the proposed changes to the extreme and uncontrollable circumstances policy for PY 2021 and subsequent performance years. The following is a summary of the comments we received and our response.

Comment: Several commenters supported our proposal to set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, to equal the 40th percentile MIPS Quality performance category score in performance year 2021. Two commenters did not support the proposed changes to the extreme and uncontrollable policy for performance year 2021. One commenter explained that ACO participants tend to have higher MIPS Quality performance category scores than non-ACO participants; therefore, setting the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance to equal the 40th percentile MIPS Quality performance would be lower than what the ACO may have earned. The other commenter stated that our proposal would effectively lower the protections for impacted ACOs and comes at a particularly tumultuous time due to the PHE for COVID–19. The commenter noted that they would support a similar policy if CMS maintained a baseline level of protection, such as the affected ACO's mean quality performance score, because this would maintain current levels of protection, which is particularly critical in the midst of the PHE for COVID–19, while also incentivizing ACOs to report data to improve their quality scores.

Several commenters encouraged CMS to apply the alternative extreme and uncontrollable circumstances policy discussed in the CY 2021 PFS proposed rule for performance year 2020 to performance year 2021. These commenters cited their concerns that the effects of the PHE for COVID–19 would extend into 2021 and urged CMS to extend this alternative policy to performance year 2021.

Other commenters urged us to refrain from making further changes to the extreme and uncontrollable circumstances policy for other performance years at this time, given that all ACOs are currently subject to the existing policy due to the PHE for COVID–19. These commenters explained that numerous changes to the extreme and uncontrollable circumstances policy were made in performance years 2019 and 2020, including additional modifications due to the PHE for COVID–19, and therefore CMS should refrain from making further changes to the policy at this time. Commenters noted that abrupt changes in policy, like changing the reporting requirements during the PHE for COVID–19, have been difficult for healthcare providers to adjust to and that these policy changes should take place only after the end of the PHE for COVID–19, once the totality of information and learnings can be assessed. The commenters suggested that we allow more time to examine the impacts of the PHE for COVID–19 and gather further stakeholder input before proceeding with any changes to the policy for performance year 2021 and subsequent years.

Response: We acknowledge that we have made multiple changes to the extreme and uncontrollable circumstances policy over the past few years in order to provide relief to ACOs impacted by extreme and uncontrollable circumstances. We also agree with the commenter that ACOs typically have higher MIPS Quality performance category scores than non-ACO MIPS participants, based on their performance on the measures reported via the CMS Web Interface and the CAHPS for ACOs; however, given that the APP measure set is smaller and includes a combination of eCQMs/CQM MIPS measures, CAHPS for MIPS and 2 claims-based measures, we have no comparisons to determine how ACOs will perform in relation to non-ACO groups under the APP. Accordingly, we believe setting the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year to equal the MIPS Quality performance category score that will satisfy the quality performance standard is appropriate and aligns with the policies regarding for the quality performance standard as discussed in section III.G.1.b.(1) of this final rule.

We note that as discussed in section III.G.1.c. of this final rule, we are finalizing a gradual phase-in of the increase in the level of quality performance standard that would be required for all ACOs to meet the Shared Savings Program quality performance standard to allow time for ACOs to gain experience. For performance years 2021 and 2022, the threshold for the quality performance standard will be set at a quality performance score equivalent to or above the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, and for performance year 2023 and subsequent performance years, the threshold for the quality performance standard will be set at a quality score equivalent to or above the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. This gradual phase-in is designed to allow ACOs to gain experience under the new standard. We agree that the extreme and uncontrollable circumstances policy should offer an appropriate level of protection for ACOs that are impacted by an extreme and uncontrollable circumstance while still incentivizing quality reporting. We believe that aligning the extreme and uncontrollable circumstances policy with the gradual phase in of the quality performance standard will offer protection for ACOs, while still incentivizing reporting. Moreover, this policy enables ACOs impacted by an extreme and uncontrollable circumstance to share in savings at their maximum sharing rate. We acknowledge that this policy change will potentially affect ACOs in Track 2 and the ENHANCED track, for whom shared losses are determined based in part on an ACO's quality performance. These ACOs, however, will have relief from shared losses through the application of the extreme and uncontrollable circumstances policy under which shared losses are reduced based on the percentage of the year and percentage of assigned beneficiaries impacted by an extreme and uncontrollable circumstance.

Although several commenters encouraged CMS to apply the alternative extreme and uncontrollable circumstances policy we sought comment on in the CY 2021 PFS

proposed rule for performance year 2020 to performance year 2021, we do not believe applying the same policy we sought comment on for performance year 2020, as described in section III.I.2 of this final rule would be appropriate for performance year 2021. We do not believe assigning the higher of an ACO's 2019 or 2021 quality score to determine an ACO's quality performance score for performance year 2021 would be an effective way to mitigate the concerns related to the PHE for COVID–19 because there would be a mismatch in the datasets and the scoring methodologies between the 2 years. One score would be based on a one to 100 scale while the other would be based on a percentile range. As a result, the scores for the 2 years would not be comparable across years. However, in this final rule, we are lowering the threshold for the quality performance standard to the 30th percentile from the initially proposed 40th percentile for performance years 2021 and 2022, and we believe this change will help to alleviate and mitigate the impact of COVID–19.

We received no comments on our proposal to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries.

For these reasons, we are finalizing our proposed changes to the extreme and uncontrollable circumstances policy for performance year 2021 and subsequent performance years with modifications and conforming changes as follows:

For PY 2021 and PY 2022, consistent with the modifications to the quality performance standard described in section III.G.1.b.(1). of this final rule, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, will be set equal to the 30th percentile MIPS Quality performance category score as determined under § 425.512(a)(3). If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 30th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 30th percentile MIPS Quality performance category score.

For PY 2023, we will set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, to equal the 40th percentile MIPS Quality performance category score as determined under § 425.512(a)(4). If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 40th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 40th percentile MIPS Quality performance category score.

For additional information, we refer readers to Table 39, in section III.G.1.b.(1) above, which shows the Shared Savings Program quality performance standard for PY 2021, PY 2022, and PY 2023.

We are finalizing our proposal to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries as proposed. We are also finalizing our proposal to specify the policies for addressing the effect of extreme and uncontrollable circumstances on ACO quality performance for performance year 2021 and subsequent performance years with the modifications and conforming changes described previously, in the new provision at § 425.512(b).

In the CY 2021 PFS proposed rule (85 FR 50240 and 50241), we also solicited comment on a potential alternative extreme and uncontrollable circumstances policy for PY 2022 and subsequent years that would continue to incentivize reporting but also acknowledge the challenges presented by extreme and uncontrollable circumstances. We explained that we were considering creating an extreme and uncontrollable circumstances methodology that would adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting. This methodology would be similar to the methodology currently used to adjust for extreme and uncontrollable circumstances when calculating the amount of shared losses for impacted ACOs. Under this alternative approach, instead of determining that ACOs are affected by an extreme and uncontrollable circumstances if 20 percent of their beneficiaries or their legal entity are located in an area impacted by an extreme and uncontrollable circumstance and determining shared savings using the higher of the ACO's own quality score and the mean ACO quality score, we would determine shared savings for an affected ACO by multiplying the maximum possible shared savings the ACO would be eligible to receive based on its financial performance and track (or payment model within a track) by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

If an ACO impacted by an extreme and uncontrollable circumstance does not report quality or reports quality, but does not meet the quality performance standard of a quality performance score equivalent to a MIPS Quality performance category score at or above the 40th percentile and owes shared losses, we noted that the existing extreme and uncontrollable circumstances methodology that applies when calculating the amount of shared losses would help to mitigate those losses.

We received public comments on this potential alternative extreme and uncontrollable circumstances policy for PY 2022 and subsequent years. The following is a summary of the comments we received and our responses.

Comment: We received two comments in support of the potential alternative extreme and uncontrollable circumstances policy for performance year 2022 and subsequent years. One commenter noted that the proposed methodology to adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting would provide affected ACOs with flexibility in reporting. The commenter emphasized that this would help ACOs continue participating in the Shared Savings Program.

Several other commenters stated that they did not support CMS making additional changes to the extreme and uncontrollable circumstances policy at this time. These commenters urged CMS to refrain from making any significant changes to the extreme and uncontrollable policy at this time and to continue to assess the impact of the PHE

for COVID–19 before making any further changes to the established policy.

Response: As we plan for future updates and changes to the extreme and uncontrollable circumstances policy for performance year 2022 and subsequent years, we will consider this feedback in the development of our proposals.

h. Technical Changes To Incorporate References To Revised Quality Performance Standard

In section III.G.1.h of the CY 2021 PFS proposed rule (85 FR 50241), we proposed to make certain technical, conforming changes to provisions of the Shared Savings Program regulations to reflect the proposal to add new sections of the regulations at § 425.510 on the application of the APP to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021, and § 425.512 on determining the ACO quality performance standard for performance years beginning on or after January 1, 2021. We did not receive comments directly addressing our proposed technical changes to incorporate references to the proposed new regulations. In this section, we specify the technical changes we are finalizing either as proposed, or with additional revisions to account for the modifications we are making to phase in the new quality performance standard for performance years beginning on or after January 1, 2021, as discussed elsewhere in section III.G.1 of this final rule.

• Under subpart A, which specifies general provisions governing the Shared Savings Program:

++ In § 425.100(b), the general description of ACOs that are eligible to receive payments for shared savings under the program, we are finalizing our proposed revisions for clarity and to add a reference to § 425.512. In the description of the quality performance standard that must be met for the ACO to be receive payment for shared savings, we are finalizing our proposal to specify that the quality performance standards established under § 425.500 are applicable for performance years (or a performance period) beginning on or before January 1, 2020, and that the quality performance standard under § 425.512 is applicable for performance years beginning on or after January 1, 2021.

++ In § 425.112(b)(2)(i), the provision specifying the ACO must have processes to promote patient engagement including to address compliance with patient experience of care survey requirements, we are finalizing our proposal to add a reference to § 425.510.

• Under subpart C, which governs application procedures and the participation agreement, we are finalizing our proposed addition of a reference to § 425.510 in the provision at § 425.200(d) specifying that ACOs must submit measures in the form and manner required by CMS.

• Under subpart D, which specifies program requirements and beneficiary protections, we are finalizing our proposed addition of a reference to § 425.510 in § 425.302(a)(1) specifying requirements for data submission and certification.

• Under subpart G, which specifies the program's financial models for determining shared savings and shared losses (as applicable), we proposed to revise the description of program requirements that phase-in over multiple agreement periods in § 425.600(f)(4). We are finalizing our proposal to revise this provision with modifications to account for the phase-in of the revised quality performance standard that we describe in section III.G.1.b and section III.G.1.c of this final rule with modifications. Specifically, we are revising this provision to account for the approach we are finalizing under § 425.512(a), which differentiates the quality performance standard applicable to ACOs in the first performance year of their first agreement period from the standard that is applicable to ACOs in subsequent years. This aspect of the phase-in of the quality performance standard applies to ACOs entering their first agreement period in the Shared Savings Program beginning on January 1, 2022, and in subsequent years, consistent with CMS' decision to forgo an application cycle for a January 1, 2021 agreement start date in the Shared Savings Program. Therefore, we are finalizing revisions to § 425.600(f)(4)(i) to add a reference to the quality performance standard as described in § 425.512(a), which will be applicable for the performance year starting on January 1, 2021, and subsequent performance years.

• Under subpart I, which governs the reconsideration review process, we are finalizing our proposed addition of references to § 425.510, § 425.512, or both to § 425.800(a)(1), (2), and (6).

2. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

a. Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) Codes Used in Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by CPT and HCPCS codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

In the June 2015 final rule (80 FR 32746 through 32748), we expanded the definition of primary care services to include two transitional care management (TCM) codes (CPT codes 99495 and 99496), and one chronic care management (CCM) code (CPT 99490). As discussed in the final rule, the TCM codes were established to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or SNF stay. Including these codes in the definition of primary care services reflects our belief that the work of community physicians and practitioners in managing a patient's care following discharge from a hospital or nursing facility (NF) to ensure better continuity of care for these patients and help

reduce avoidable readmissions is a key aspect of primary care.

In the CY 2016 PFS final rule (80 FR 71270 through 71273), we revised the definition of primary care services to exclude services billed under CPT codes 99304 through 99318, containing the place of service 31 modifier specifying that the service was furnished in a SNF. We also revised the definition of primary care services to include claims submitted by Electing Teaching Amendment (ETA) hospitals.

In the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional CCM service codes, 99487, 99489, and G0506, and four behavioral health integration (BHI) service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). We further revised the definition of primary care services in the November 2018 final rule. In the November 2018 final rule, we added new codes to the definition of primary care services (CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443), and revised how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF (83 FR 59964 through 59968).

For performance years beginning on January 1, 2019, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(iv) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a NF; services identified by these codes furnished in a SNF are excluded).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for E/M services furnished in a patients' home for claims identified by place of service modifier 12).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

(7) 99497 and 99498 (codes for advance care planning).

(8) 96160 and 96161 (codes for administration of health risk assessment).

(9) 99354 and 99355 (add-on codes, for prolonged E/M or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code).

(10) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0463 (for services furnished in ETA hospitals).

(4) G0506 (code for chronic care management).

(5) G0444 (codes for annual depression screening service).

(6) G0442 (code for alcohol misuse screening service).

(7) G0443 (code for alcohol misuse counseling service).

In the May 8th COVID–19 IFC (85 FR 27582 through 27586), we revised the regulations to add § 425.400(c)(2), specifying the definition of primary care services for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19 defined in § 400.200, to include the foregoing codes specified in § 425.400(c)(1)(iv), as well as specified codes for remote evaluations, virtual check-ins, e-visits, and telephone E/M services. In section III.G.5.e of this final rule, we discuss the final policies regarding the definition of primary care services during the PHE for COVID–19.

(2) Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we discussed in the CY 2021 PFS proposed rule (85 FR 50242 through 50248) our belief that it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and make other technical changes to the definition of primary care services, for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years.

We proposed to revise the definition of primary care services in the Shared Savings Program regulations to include the following additions: (1) Online digital E/M CPT codes 99421, 99422, and 99423; (2) assessment of and care planning for patients with cognitive impairment CPT code 99483; (3) chronic care management code CPT code 99491; (4) non-complex chronic care management HCPCS code G2058 and its proposed replacement CPT code, if finalized through the CY 2021 PFS rulemaking; (5) principal care management HCPCS codes G2064 and G2065; and (6) psychiatric collaborative care model HCPCS code GCOL1, if finalized through the CY 2021 PFS rulemaking.

The following provides additional information about the CPT and HCPCS codes that we proposed to add to the definition of primary care services used in assignment:

• *Online Digital Evaluation and Management Services (CPT codes 99421, 99422, and 99423):* In the CY 2020 PFS final rule (84 FR 62797), we finalized payment for new online digital assessment services, also referred to as ''E-Visits,'' beginning in CY 2020 for practitioners billing under the PFS. These services are non-face-to-face, patient-initiated communications using online patient portals. These digital assessment services are for established patients who require a clinical decision that otherwise typically would have been provided in the office. Practitioners who may independently bill Medicare for E/M services (for instance, physicians and NPs) can bill the following codes:

++ *99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.)*

++ *99422 (Online digital evaluation and management service, for an established patient, for up to 7 days cumulative time during the 7 days; 11–20 minutes.)*

++ *99423 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.)*

In the May 8th COVID–19 IFC (85 FR 27583), we stated that we believe it is appropriate to include these CPT and HCPCS codes in the definition of primary care services used for assignment for PY 2020 and any subsequent performance year that starts during the PHE for COVID–19 because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We also explained our belief that it is important to include these services in our assignment methodology because we determine assignment to ACOs based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting

assigned beneficiary population. Subsequent to the publication of the May 8th COVID–19 IFC, we have determined, based on the justification above, that these codes should be included in the definition of primary care services under § 425.400(c) permanently for purposes of determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years, and should not be linked to the duration of the PHE for COVID–19.

• *Assessment of and care planning for patients with cognitive impairment (CPT code 99483):* In the CY 2017 PFS final rule (81 FR 80252–54), we finalized a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, such as from Alzheimer's disease or dementia, at any stage of impairment, G0505 (*Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home*). In the CY 2018 PFS final rule (82 FR 53077), we deleted the interim HCPCS code G0505 and replaced it with CPT code 99483 (*Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (e.g., Basic and Instrumental Activities of Daily Living), including decision-making capacity; Use of standardized instruments for staging of dementia (e.g., Functional Assessment Staging Test [FAST], Clinical Dementia Rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (e.g., home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family caregiver*).

CPT code 99483 includes the same elements included in the Level 5 E/M service CPT code 99215, such as, a comprehensive history, comprehensive exam, and high complexity medical decision-making. CPT code 99215 is included in the definition of primary care services used for assignment. Accordingly, we noted in the proposed rule that we believe it would be appropriate to also include CPT code 99483 in the definition of primary care services used for assignment under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years.

• *Chronic Care Management (CPT code 99491):* In the CY 2019 PFS final rule (83 FR 59577), we finalized CPT code 99491 (*Chronic care management services, provided personally by a physician or other qualified healthcare professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*). This code requires two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, and that a comprehensive care plan has been established, implemented, revised or monitored by the billing practitioner for such patient. In earlier rulemaking, we finalized the inclusion of CCM CPT codes 99487, 99489, and 99490 (codes for chronic care management) in the definition of primary care services for the Shared Savings Program. Refer to the June 2015 final rule (80 FR 32746 through 32748), and CY 2018 PFS final rule (82 FR 53212 through 53213). ''Non-complex'' CCM services (CPT codes 99490 and 99491), and ''complex'' CCM services (CPT codes 99487 and 99489) share a common set of service elements, including the following: (1) Initiating visit, (2) structured recording of patient information using certified electronic health record technology (EHR), (3) 24/7 access to physicians or other qualified health care professionals or clinical staff and continuity of care, (4) comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs, (5) comprehensive care plan including a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed, and (6) management of care transitions. They differ in the amount of clinical staff service time provided, the involvement and work of the billing practitioner, and the extent of care planning performed.[65] CPT code 99491 includes only time that is spent personally by the billing practitioner. Clinical staff time is not counted towards the required time threshold for reporting this code, whereas CPT codes 99487, 99489, and 99490 include time spent directly by the billing practitioner and by other clinical staff that counts toward the threshold clinical staff time required to be spent during a given month. Accordingly, CPT code 99491 cannot be reported for a beneficiary by a billing practitioner in the same month as CCM codes 99487, 99489, or 99490. Therefore, we noted in the proposed rule that we believe it would be appropriate to propose to include CCM CPT code 99491 in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years, in order to capture these CCM services when attributing beneficiaries to an ACO.

• *Non-Complex CCM (HCPCS code G2058 and its proposed replacement CPT code):* In the CY 2020 PFS final rule (84 FR 62690), we finalized the creation of HCPCS code G2058 *(Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Do not report G2058 for care management services of less than 20 minutes additional to the first 20 minutes of chronic care management services during a calendar month). (Use G2058 in conjunction with 99490). (Do not report 99490, G2058 in the same calendar month as 99487, 99489, 99491))* for additional time spent beyond the initial 20 minutes included in the current coding for CCM services. As described in the CY 2021 PFS proposed rule, we proposed the

[65] Refer to CMS Medicare Learning Network, MLN Booklet ''Chronic Care Management Services'' (ICN MLN909188, July 2019); available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf.*

adoption of the permanent CPT code to replace HCPCS code G2058. As described in previous rulemaking, practitioners who choose to use G2058 can report the initial 20 minutes of non-complex CCM under CPT code 99490 and receive increased payment for their work under HCPCS code G2058 (84 FR 62690). Since CPT code 99490 is currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(1)(iv), we proposed to add G2058 to the definition, effective for performance years starting on or after January 1, 2021, because the services furnished during the additional time billed under HCPCS code G2058, would be expected to be substantially similar to the services furnished under CPT code 99490, and thus should also be considered for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years. In the CY 2021 PFS proposed rule, we stated that, if the proposal to adopt the permanent CPT code to replace HCPCS code G2058 is finalized, we would instead include that CPT code in the definition of primary care services used for purposes of assignment under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years. Elsewhere in this rule, we discuss the finalization of 99439 (*Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) as the permanent CPT code to replace G2058.

• *Principal Care Management (HCPCS codes G2064 and G2065):* The CY 2020 PFS final rule (84 FR 62692 through 62697) introduced two new HCPCS codes (G2064 and G2065) for Principal Care Management (PCM) services. G2064 *(Comprehensive care management services for a single high-risk disease, e.g., principal care management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities),* for use by physicians and NPPs, and G2065 *(Comprehensive care management for a single high-risk disease services, e.g. principal care management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities),* for use by clinical staff.

As discussed in the proposed rule, we expect that most services billed under these codes will be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. HCPCS code G2064 would be reported when, during the calendar month, at least 30 minutes of physician or other qualified health care professional time is spent on comprehensive care management for a single high-risk disease or complex chronic condition. HCPCS code G2065 would be reported when, during the calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high-risk disease or complex chronic condition. Comprehensive care management codes require patients to have two or more chronic conditions and are primarily billed by practitioners who are managing a patient's total care over a month, including primary care practitioners and some specialists, such as cardiologists or nephrologists. By contrast, PCM services involve care management services for one serious chronic condition, typically expected to last between 3 months and a year, or until the death of the patient, that may have led to a recent hospitalization, and/or places the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Specifically, we stated in the CY 2020 PFS final rule (84 FR 62693 through 62697) that we agree that the relativity between CCM CPT codes 99490 and 99491 should be preserved in PCM HCPCS codes G2064 and G2065 and crosswalked the RVUs for G2064 and G2065 to 99491 and 99490, respectively. Due to the similarity between the description of the PCM and CCM services, both of which involve non-face-to-face care management services, we finalized that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. CCM services billed under code 99490 are currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(1)(iv), and as discussed previously, we proposed to include CCM services billed under code 99491 for performance years starting on or after January 1, 2021; therefore, for the foregoing reasons, we also proposed to add G2064 and G2065 to the definition of primary care services for the performance year starting on January 1, 2021, and subsequent performance years.

• *Psychiatric collaborative care model HCPCS code GCOL1:* In the CY 2017 PFS final rule (81 FR 80230–36), we established G-codes used to bill for monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99484, 99492, 99493, and 99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077 and 53078).

As discussed in the proposed rule, we proposed to add a new HCPCS code GCOL1 *(Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional)* in response to stakeholders who have requested additional coding to capture shorter increments of time spent, for example, when a patient is seen for services, but is then hospitalized or referred for specialized care, and the number of minutes required to bill for services using the current coding is not met. Specifically, we proposed to establish a G-code to describe 30 minutes of behavioral health care manager time. This code would describe one-half of the time described by the existing code that describes subsequent months of CoCM services, CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified*

health care professional, with the following required elements:

- *Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant;*
- *Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;*
- *Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;*
- *Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;*
- *Monitoring of patient outcomes using validated rating scales; and*
- *Relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment*).

Because CPT code 99493 is currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(iv), we believe it is appropriate to add GCOL1 to the definition since the services furnished under the proposed new code would be expected to be substantially similar to the services furnished under CPT code 99493. Accordingly, contingent upon its finalization, we proposed to add HCPCS code GCOL1 to the definition of primary care services for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years. HCPCS code GCOL1 is being finalized as HCPCS code G2214 (*Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional*), as discussed elsewhere in this final rule.

In the May 8th COVID–19 IFC (85 FR 27583), we revised the definition of primary care services used in the Shared Savings Program assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19, as defined in § 400.200, to include the following additions: (1) HCPCS code G2010 (*remote evaluation of patient video/images*); (2) HCPCS code G2012 (*virtual check-in*); and (3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*).

We considered adding HCPCS codes G2010 *(Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment)* and G2012 *(Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion)* to the definition of primary care services for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years; however, while we recognized the importance of the flexibility these HCPCS codes provide during the PHE for COVID–19, we explained in the proposed rule that we do not believe they should be added to definition of primary care services for purposes of assignment under § 425.400 on a permanent basis. In the context of the PHE for COVID–19, when brief communications with practitioners and other non-face-to-face services could mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, healthcare providers, and individuals in the community, we concluded that it was appropriate to include HCPCS codes G2010 and G2012 in the definition of primary care services used in assignment. However, outside the context of the PHE for COVID–19, we expect that these monitoring/check-in services for established patients will no longer replace primary care services because these separately billable brief communication-technology based services describe a check-in directly with the billing practitioner to assess whether an office visit is needed. When the PHE for COVID–19 ends, these services would likely be replaced by an in-person primary care visit on which assignment would be based.

We sought comment on this issue and on the alternative approach of permanently including HCPCS codes G2010 and G2012 in the definition of primary care services used in assignment. We noted that we would consider the comments received in developing the policies for the final rule.

We noted that we did not consider including CPT codes 99441, 99442, and 99443 in the definition of primary care services at § 425.400(c) on a permanent basis. Telephone E/M services CPT codes 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.*); 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion.*); and 99443 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion.*) are non-covered services when not provided during the PHE for COVID–19, as defined in § 400.200, and so could not be included in the definition of primary care services for purposes of assignment outside the context of the PHE.

We also proposed to modify the definition of primary care services for purposes of assignment in the Shared Savings Program regulations to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting, for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. In the November 2018 final rule (83 FR 59964 through 59968), we finalized the inclusion of CPT code 99497 and the add-on code 99498 in the definition of primary care services. We did not propose any exceptions to place of service or provider type because there

are no facility setting limitations or provider specialty limitations on these codes.[66] In the CY 2021 PFS proposed rule (85 FR 50245), we explained that since adding these codes to the definition of primary care services we have received feedback from an ACO that, by not restricting place of service when using advance care planning codes in assignment, our methodology may inappropriately assign beneficiaries. Specifically, we described our concern that the inclusion of these CPT codes when the services are provided in an inpatient care setting may result in beneficiaries being assigned based on inpatient care rather than based on primary care by their regular healthcare providers. Based on an initial analysis using calendar year 2019 claims data, we observed the following frequencies for occurrence of place of service code 21, which identifies the place of service as an inpatient hospital, with CPT codes 99497 and 99498 in Part B claims: Over 13 percent of approximately 1.6 million Part B claims for CPT code 99497 had place of service code 21; over 48 percent of approximately 43,000 Part B claims for CPT code 99498 had place of service code 21. We explained that operationally we would exclude advanced care planning services claims billed under CPT codes 99497 and 99498 from use in the assignment methodology when there is an inpatient facility claim in our claims files with dates of service that overlap with the date of service for the professional service billed under CPT code 99497 or add-on code 99498. A similar operational approach is currently used to exclude certain codes for professional services furnished in a SNF pursuant to § 425.400(c)(1)(iv)(A)(*2*), as described in the proposed rule.

We also sought comment on an alternative method for determining operationally whether advance care planning services are provided in an inpatient care setting. Specifically, we sought comment on whether to exclude advance care planning services identified by CPT code 99497 or add-on code 99498, or both, reported on claims with place of service code 21, which identifies the place of service as an inpatient hospital.[67] We explained that based on initial analysis, we had determined that this alternative approach would capture slightly fewer claims for advance care planning, compared to the proposed approach. We noted that we would consider any comments received on this alternative approach in developing our policies for the final rule.

We proposed to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(v) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(iv) with the proposed additional CPT and HCPCS codes, and reflecting the proposal to exclude advance care planning codes when provided in an inpatient setting in the new provision at § 425.400(c)(1)(v)(A)(*12*). We also proposed that the new provision in § 425.400(c)(1)(v) would reflect technical modifications to the previously finalized descriptions of the CPT and HCPCS codes for consistency and clarity, including grammatical updates and ordering the codes sequentially. We proposed the new provision at § 425.400(c)(1)(v) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. Further, we proposed technical modifications to the introductory text in § 425.400(c)(1)(iv) to specify the applicability of this provision for determining beneficiary assignment for performance years (or a performance period) during 2019 and performance year 2020.

We sought comment on the proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2021, and subsequent performance years. We also sought comments on any other existing HCPCS or CPT codes, and new HCPCS or CPT codes proposed in the CY 2021 PFS proposed rule, that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We noted that, under § 425.212, an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute: (1) Eligibility requirements concerning the structure and governance of ACOs; and (2) calculation of sharing rate. As we have explained in earlier rulemaking, consistent with our authority under section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and other factors as the Secretary determines appropriate, CMS adjusts an ACO's historical benchmark to account for any regulatory changes affecting assignment during the agreement period (80 FR 32730 through 32732). Accordingly, we stated in the proposed rule that, if we finalized any of the proposed changes to the definition of primary care services discussed in section III.G.2. of the CY 2021 PFS proposed rule for purposes of beneficiary assignment applicable for the performance year starting on January 1, 2021, and subsequent performance years, we would adjust ACOs' historical benchmarks to account for these changes. Although it has been our historical practice to make these adjustments, the regulations establishing our benchmarking methodology do not explicitly describe these adjustments. Accordingly as discussed in the CY 2021 PFS proposed rule, we proposed conforming revisions to the regulations in §§ 425.601(a)(9), 425.602(a)(8), and 425.603(c)(8), to specify that CMS will adjust the ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in part 425, subpart E during an ACO's agreement period including revisions to the definition of primary care services in § 425.400(c). Further, in light of the proposed changes, we proposed to make certain other technical changes to §§ 425.601, 425.602, and 425.603 for clarity and internal consistency.

We received public comments on the proposed revisions to HCPCS and CPT codes used for purposes of assignment in the Shared Savings Program regulations. The following is a summary of the comments we received and our responses.

Comment: Most commenters were generally supportive of our proposals regarding the expansion of the definition of primary care services for purposes of assignment in the Shared Savings Program regulations. Many comments indicated that the PHE for COVID–19 has led healthcare providers to expand their provision of services via telehealth, which has allowed beneficiaries to access to many services that otherwise might have been foregone due to the PHE. Furthermore, some commenters suggested that increased delivery of services via telehealth is likely to continue after the PHE, as healthcare providers and patients are increasingly accustomed to this service delivery modality and have found it to be a convenient and appropriate means for delivery of certain healthcare services. A few commenters noted it is vital that ACOs are held responsible for the correct cohort of patients, and these

[66] Refer to CMS, Medicare Learning Network, ''Advance Care Planning'' (ICN MLN909289, August 2019); available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf*.

[67] See for example, *CMS.gov*, Place of Service Code Set (updated October 2019); available at *https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set*.

changes to the definition of primary care services would help to 'move the needle' in that direction. One commenter stated that it has increased its provision of telehealth services exponentially due to the PHE and expects that the volume of these types of visits will remain elevated even after the PHE ends. This commenter stated its belief that these changes will be necessary to accurately reflect the Medicare patient population's health care utilization patterns going forward.

While most commenters supported the addition of Principal Care Management (PCM) codes G2064 and G2065 to the list of primary care services, a few commenters did not support adding the PCM codes. These commenters noted that these codes will primarily be used by specialists and while the scope and description of services for CCM and PCM may be similar, it does not necessarily follow that both services should be considered primary care services.

Response: We appreciate the commenters' support for our proposal to revise the definition of primary care services used for assignment under the Shared Savings Program regulations to include the following additions: (1) Online digital E/M CPT codes 99421, 99422, and 99423; (2) assessment of and care planning for patients with cognitive impairment CPT code 99483; (3) chronic care management code CPT code 99491; (4) non-complex chronic care management HCPCS code G2058 and its replacement CPT code 99439; (5) principal care management services HCPCS codes G2064 and G2065; and (6) psychiatric collaborative care model HCPCS code GCOL1, which is being finalized as HCPCS code G2214, as discussed elsewhere in this final rule. We agree that expanding the definition of primary care services used for beneficiary assignment will allow for more accurate assignment. While we appreciate the concerns raised by commenters regarding the addition of PCM codes G2064 and G2065, due to the similarity between the description of the PCM and CCM services, we continue to believe that these codes are a valuable addition to the definition of primary care services used for beneficiary assignment, because the full CCM scope of service requirements apply to PCM, and the CCM services are included in the Shared Savings Program's current definition of primary care services under § 425.400(c)(1)(iv). Additionally, consistent with our current methodology, if services billed under these codes are provided by specialists not used in the Shared Savings Program beneficiary assignment methodology, then they will not be included in beneficiary assignment. Therefore, we are finalizing our proposal to incorporate the aforementioned codes into the definition of primary care services that will be used in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. We are also finalizing our proposal to specify the updated definition of primary care services in a new provision of the regulations at § 425.400(c)(1)(v).

Comment: Several commenters supported the permanent addition of the remote evaluation of patient video/images (G2010) and virtual check-in (G2012) HCPCS codes to the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2021. These commenters indicated that virtual check-ins and remote evaluation of patient video/images are communications-based technology services that have proven their value across the disease spectrum and care continuum and should continue to be included in the definition of primary care services used for assignment after the PHE ends.

Response: We appreciate the comments in support of the permanent addition of the remote evaluation of patient video/images (G2010) and virtual check-in (G2012) HCPCS codes to the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2021. In the CY 2021 PFS proposed rule (85 FR 50245), we stated that, outside the context of the PHE for COVID–19, we did not expect these monitoring/check-in services for established patients to replace primary care services. This was because these separately billable brief communication-technology based services describe a check-in directly with the billing practitioner to assess whether an office visit is needed; and we believed that when the PHE for COVID–19 ends, these services would likely be replaced by an in-person primary care visit on which assignment would be based. However, based on comments received anticipating that healthcare providers will continue to provide the services identified by G2010 and G2012 and that there will continue to be an uptake of services identified by these codes in lieu of an in-person primary care visit by the beneficiary even following the end of the PHE for COVID–19, we are persuaded that including G2010 and G2012 in the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2021, would result in more accurate assignment of beneficiaries based on where they receive the plurality of their primary care services. We are therefore adding HCPCS codes G2010 and G2012 to the definition of primary care services for purposes of beneficiary assignment in the Shared Savings Program for the performance year starting on January 1, 2021, and subsequent performance years, as specified in the regulations at § 425.400(c)(1)(v).

Comment: Several commenters supported our proposal to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting. These commenters appreciated the concern that codes billed in an inpatient setting in the beneficiary assignment methodology may result in beneficiaries being assigned to an ACO based on inpatient care, rather than on primary care. However, one commenter was concerned that removing these services from the definition of primary care services used for assignment may inadvertently discourage healthcare provider from furnishing these services in inpatient settings. This commenter stated that evidence shows that usage of these billing codes is low, even though most Americans do not have advance directives. Therefore, the commenter suggested that advance care planning should be promoted, not in any way discouraged. Commenters also appreciated CMS' desire to ensure that beneficiaries are attributed to the ACOs from whom they receive their primary care services.

Response: We appreciate the support from commenters regarding our proposal to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting, for purposes of determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. Although we do not want to discourage the provision of advance care planning services or the appropriate use of the associated advance care planning codes, we do not believe that these services, when provided in an inpatient setting represent primary care services that should be used in assignment. In particular, we continue to have concerns that including these codes when billed in an inpatient setting may result in beneficiaries being assigned to an ACO based on inpatient care, rather than on primary care. By this, we mean that a beneficiary could be assigned to the ACO with which the physician providing inpatient care is associated,

which may be different from the ACO in which the physician from which the beneficiary typically receives primary care services in the community is participating, which could be disruptive to the beneficiary's overall care management. Therefore, we are finalizing our proposal to specify in § 425.400(c)(1)(v)(A)(*12*) that advance care planning services identified by CPT code 99497 and add-on code 99498 are excluded when furnished in an inpatient setting.

We did not receive comments regarding our proposal to exclude advanced care planning services claims billed under CPT codes 99497 and 99498 from use in the assignment methodology when there is an inpatient facility claim in our claims files with dates of service that overlap with the date of service for the professional service billed under CPT code 99497 or add-on code 99498. We also did not receive comments regarding the potential alternative method for determining whether advance care planning services are provided in an inpatient care setting. Specifically, we sought comment on whether to exclude advance care planning services identified by CPT code 99497 or add-on code 99498, or both, reported on claims with place of service code 21, which identifies the place of service as an inpatient hospital. Accordingly, we are finalizing as proposed the operational approach of excluding advanced care planning services claims billed under CPT codes 99497 and 99498 from use in the assignment methodology when there is an inpatient facility claim in our claims files with dates of service that overlap with the date of service for the professional service billed under CPT code 99497 or add-on code 99498. This operational approach is similar to the operational approach currently used to exclude certain codes for professional services furnished in a SNF under § 425.400(c)(1)(iv)(A)(*2*) and, as we discussed in the CY 2021 PFS proposed rule (85 FR 50246) captures slightly more claims than the alternative proposed approach We believe this more inclusive approach is appropriate in order to ensure that beneficiaries are assigned based on primary care services, not inpatient care services.

Comment: We received a couple of comments suggesting that CMS add the Primary Care Add-on HCPCS Code GPC1X, which is being finalized as HCPCS code G2211, as discussed elsewhere in this final rule, and the new Prolonged Services Add-on CPT Code 99417 (when the base code is also a primary care service code) to the list of primary care services used for assignment.

Response: We appreciate the feedback from commenters on our comment solicitation regarding any existing HCPCS or CPT codes and new HCPCS or CPT codes proposed in the CY 2021 PFS proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking. HCPCS G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*) and prolonged visit add-on CPT code 99417 (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)*) are used to report prolonged care provided to beneficiaries as an add-on to an E/M service. Under Medicare FFS payment policy, G2211 may be used in combination with certain E/M codes for new or established patients, including CPT codes 99201 through 99215, which are included within the definition of primary care services used for beneficiary assignment as specified under § 425.400(c).

Because we did not discuss adding add-on HCPCS Code G2211 and the prolonged services add-on CPT Code 99417, formerly CPT code 99XXX, to the list of primary care services used for assignment in the CY 2021 PFS proposed rule, we cannot finalize the inclusion of these codes in the definition of primary care services used for beneficiary assignment as specified under § 425.400(c), for the performance year beginning January 1, 2021, and subsequent performance years. We agree with commenters that G2211 and 99417 seem to fit within the definition of primary care services used for beneficiary assignment as specified under § 425.400(c). We will continue to evaluate and may consider the addition of these codes in future rulemaking.

In summary, after considering comments we received, we are finalizing the proposed definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years, with a modification to include G2010 and G2012 in the definition of primary care services used in assignment. We are finalizing this definition in a new provision of the regulations at § 425.400(c)(1)(v), which includes the HCPCS and CPT codes specified in § 425.400(c)(1)(iv), as well as the following additional codes, and limitations on the use of certain codes:

- Online digital E/M CPT codes 99421, 99422, and 99423;
- Assessment of and care planning for patients with cognitive impairment CPT code 99483;
- Chronic care management code CPT code 99491;
- Exclusion of advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting;
- Remote evaluation of patient video/images HCPCS codes G2010;
- Virtual check-in HCPCS code G2012;
- Non-complex chronic care management HCPCS code G2058 and its replacement CPT code 99439 as finalized elsewhere in this final rule;
- Principal care management HCPCS codes G2064 and G2065; and
- Psychiatric collaborative care model HCPCS code GCOL1, which is being finalized as HCPCS code G2214, as discussed elsewhere in this final rule.

We did not receive comments specifically addressing our proposals for technical modifications, which we are finalizing without modification. Specifically, we are finalizing as proposed the technical modifications to the introductory text in § 425.400(c)(1)(iv) to specify the applicability of this provision for determining beneficiary assignment for performance years (or a performance period) during 2019 and performance year 2020. We are also finalizing the proposal to include technical modifications to the previously finalized descriptions of the CPT and HCPCS codes for consistency and clarity, including grammatical updates and ordering the codes sequentially, in the new provision at § 425.400(c)(1)(v).

We did not receive comments on our proposed conforming revisions to the regulations at §§ 425.601(a)(9), 425.602(a)(8), and 425.603(c)(8), to specify that CMS will adjust the ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in part 425, subpart E during an ACO's agreement period including revisions to the

definition of primary care services in § 425.400(c). Further, we did not receive comments on our proposed technical changes to §§ 425.601, 425.602, and 425.603 for clarity and internal consistency. We are finalizing these proposals without modification.

b. Exclusion From Assignment of Certain Services Reported by FQHCs or RHCs When Furnished in Skilled Nursing Facilities (SNFs)

(1) Background

As we described in section III.G.2.a.(1) of the proposed rule, under the Shared Savings Program, we define primary care services in § 425.400(c)(1) and (2) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the specified HCPCS and CPT codes. In the November 2018 final rule (83 FR 59965 through 59968), we finalized a policy, specified in the regulation at § 425.400(c)(1)(iv)(A)(*2*) and effective for performance years starting on January 1, 2019, and subsequent performance years, to exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. As described in the earlier rulemaking, CPT codes 99304 through 99318 are used for reporting E/M services furnished by physicians and other practitioners in a SNF or NF (83 FR 59964).

In the November 2018 final rule, we explained our operational approach to excluding CPT codes 99304 through 99318 from use in the assignment methodology when such services are furnished in a SNF. We explained that we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service (83 FR 59967). This exclusion methodology replaced the prior approach, established through earlier rulemaking (80 FR 71271 and 71272), which excluded from the definition of primary care services claims billed under CPT codes 99304 through 99318 when the claim included the place of service code 31 modifier, specifying that the service was furnished in a SNF.

In earlier rulemaking (see for example, 83 FR 59964 and 59965), we have explained our belief that excluding from assignment certain services rendered to beneficiaries during a SNF stay is appropriate because it helps to ensure that beneficiaries who receive care in a SNF are assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the primary care needs of these beneficiaries. We previously explained that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their primary care needs.

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, requires the Secretary to assign beneficiaries to ACOs participating in the Shared Savings Program based not only on their utilization of primary care services furnished by ACO professionals who are physicians but also on their utilization of services furnished by FQHCs and RHCs, effective for performance years beginning on or after January 1, 2019. The statute provides the Secretary with broad discretion to determine how to incorporate services provided by FQHCs and RHCs into the Shared Savings Program beneficiary assignment methodology.

In earlier rulemaking, we established and modified special assignment conditions for FQHCs and RHCs (see for example, 82 FR 53210 through 53212). According to § 425.404(b), for performance years starting on January 1, 2019, and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC or RHC claim as a primary care service performed by a primary care physician. Therefore, according to the Shared Savings Program's step-wise claims-based assignment methodology, as specified in § 425.402(b), all services furnished by an FQHC or RHC to a beneficiary eligible for assignment to an ACO are considered in the first step of the assignment methodology. As specified in § 425.402(b)(3), under this first step, a beneficiary eligible for assignment is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

Currently, the exclusion from beneficiary assignment of professional services claims with CPT codes 99304 through 99318, when there is an overlapping SNF stay, does not apply to services billed through FQHCs/RHCs. Because FQHC/RHC claims are submitted to CMS using institutional claim forms, we currently do not exclude these FQHC/RHC claims from assignment when a service billed under CPT codes 99304 through 99318 is provided concurrently with a SNF stay, as when claims for services billed under these codes are submitted by physicians and other practitioners. Rather, consistent with the requirement in § 425.404(b), we consider all FQHC/RHC claims for purposes of beneficiary assignment.

(2) Revisions

As discussed in the CY 2021 PFS proposed rule (85 FR 50247), an ACO has raised concerns that our methodology for excluding primary care services billed under CPT codes 99304 through 99318 from use in beneficiary assignment when provided during a beneficiary's stay in a SNF does not apply to these services when billed by FQHCs. The ACO described a circumstance where ACO professionals, billing through ACO participant FQHCs, submitted claims using CPT codes 99304 through 99318 for services provided to patients in SNFs. Specifically, the ACO participant FQHCs' physicians provided services billed under these codes to beneficiaries in community SNFs. Following discharge from the SNF, these beneficiaries returned to receiving care from their regular primary care physicians (outside the ACO). However, because the SNF exclusion for services billed under CPT codes 99304 through 99318 does not apply to services furnished by FQHCs/RHCs, these beneficiaries were assigned to the ACO in which the FQHC was an ACO participant based on the services rendered in the SNF. We believe this result is contrary to the original intention of our policy of excluding claims billed under CPT codes 99304 through 99318 for professional services furnished during a SNF stay from consideration in the assignment methodology, as described in the background for this section.

Section 1899(c)(1) of the Act provides discretion for the Secretary to determine the appropriate method to utilize services provided by FQHCs and RHCs in conducting assignment for performance years beginning on or after January 1, 2019. As discussed in the proposed rule, we believe it is important

to exclude claims for FQHC and RHC services that include CPT codes 99304 through 99318 from use in assignment when there is a SNF facility claim in our claims files with a date of service that overlaps with the date of FQHC or RHC services. Consistent with the previously established exclusion for claims billed under these codes when the services are provided to beneficiaries with an overlapping SNF stay, we believe it is important to exclude the same services from use in assignment when they are furnished by physicians and NPPs billing through an FQHC or RHC to beneficiaries in a SNF. As we explained in the CY 2021 PFS proposed rule, this approach would better recognize that beneficiaries who receive care from physicians and NPPs billing through an FQHC or RHC during a SNF stay are expected to return to receiving primary care from the health care professionals typically responsible for meeting their primary care needs when they transition back into the community.

Therefore, we proposed to revise the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF. Operationally, the exclusion would occur when the following conditions are met:

(1) Either a professional service is billed under CPT codes 99304 through 99318, or an FQHC/RHC submits a claim including a qualifier CPT code 99304 through 99318; and

(2) A SNF facility claim is in our claims files with dates of service that overlap with the date of service for the professional service or FQHC/RHC service.

As discussed in section III.G.2.a.(2) of the proposed rule, we proposed to incorporate the revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(v), applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. As part of this revised definition, we proposed to incorporate the proposed revisions to the exclusion for CPT codes 99304 through 99318 when services are furnished in a SNF at § 425.400(c)(1)(v)(A)(*3*) to extend the exclusion to services identified by these codes reported on an FQHC or RHC claim when furnished in a SNF. We proposed that this revision would also be applicable to determining assignment for the performance year starting on January 1, 2021, and subsequent performance years.

As we explained in section III.G.2.a.(2) of the proposed rule, we adjust the ACO's historical benchmark for changes in the program's assignment methodology occurring during the ACO's agreement period. We stated in the proposed rule that, if we finalized the proposed exclusion from beneficiary assignment of services reported by FQHCs or RHCs on claims that include CPT codes 99304 through 99318, when furnished in a SNF, we would adjust ACOs' historical benchmarks to account for these changes.

Further, we noted that we believe the existing process is appropriately excluding from assignment professional services billed under CPT codes 99304 through 99318 when these services are provided to beneficiaries receiving SNF services in swing beds in Critical Access Hospitals (CAHs) or Electing Teaching Amendment (ETA) hospitals. Based on our operational experience:

- We exclude professional services billed under CPT codes 99304 through 99318 when such services are furnished for care of a beneficiary in a CAH swing bed; however, relatively few claims are identified for exclusion on this basis.
- We do not believe that ETA hospitals are billing for services furnished to beneficiaries in a SNF or swing bed setting by physicians and other practitioners that have reassigned their billing rights to ETA hospitals.

However, we solicited comment on whether additional exceptions are needed to ensure that all claims for services that include CPT codes 99304 through 99318 are excluded from assignment when those services are furnished to a beneficiary receiving SNF care, including when these professional services are billed by a Method II CAH or ETA hospital.

We received public comments on the proposed revisions to exclude from assignment certain services reported by FQHCs or RHCs when furnished in SNFs. We received no comments regarding additional exceptions that may be needed to ensure that all claims for services that include CPT codes 99304 through 99318 are excluded from assignment when those services are furnished to a beneficiary receiving SNF care, including when these professional services are billed by a Method II CAH or ETA hospital.

The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of CMS' proposal to exclude professional services furnished by FQHCs or RHCs when delivered in a SNF, for purposes of assignment. Several commenters stated that this policy would ensure parity between FQHC practitioners, including physicians, and practitioners who practice in other settings, with respect to this issue. One commenter stated that, because FQHCs do not use place of service codes or other indicators that would demonstrate that a claim is eligible for exclusion, their claims are always considered primary care claims under current policy, even when the services are furnished in a SNF. These claims are then used for ACO beneficiary attribution, to the disadvantage of ACOs that include FQHCs as participants. Commenters noted that the proposed change, while technical in nature, would result in more accurate beneficiary assignment lists for ACOs.

Response: We agree with commenters that this policy will allow for more accurate assignment of beneficiaries. Accordingly, we are finalizing our proposal to revise the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF. By finalizing this policy, we will have a more consistent and accurate assignment approach. We are finalizing the definition of primary care services for use in beneficiary assignment for performance years starting on January 1, 2021, and subsequent performance years in the regulations at § 425.400(c)(1)(v), which includes the codes for professional services furnished in a nursing facility (CPT codes 99304 through 99318) at § 425.400(c)(1)(v)(A)(*3*). The provision at § 425.400(c)(1)(v)(A)(*3*) specifies that professional services or services reported on an FQHC or RHC claim identified by these codes are excluded from the definition of primary care services when furnished in a SNF.

3. Reducing the Amount of Repayment Mechanisms for Eligible ACOs

a. Background

An ACO that will participate in a two-sided model must demonstrate that it has established an adequate repayment mechanism to provide CMS assurance of its ability to repay shared losses for which the ACO may be liable upon reconciliation for each performance year. The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in § 425.204(f), and we have provided additional program guidance on

repayment mechanism arrangements.[68] We established the repayment mechanism requirements through earlier rulemaking,[69] and recently modified the repayment mechanism requirements in the December 2018 final rule (83 FR 67928 through 67938).

According to § 425.204(f)(4)(iv), in the case of an ACO that has submitted a request to renew its participation agreement and wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to the greater of the following: (1) The amount calculated by CMS in accordance with § 425.204(f)(4)(ii) at the time of renewal application; or (2) the repayment mechanism amount that the ACO was required to maintain during the last performance year of the participation agreement it seeks to renew. This approach ensures that a renewing ACO would remain capable of repaying losses incurred under its old agreement period (83 FR 67931). Based on our operational experience with implementing these policies, of 55 renewing two-sided model ACOs for a July 1, 2019, or January 1, 2020 start date, 43 ACOs (or 78.2 percent) elected to continue use of their existing repayment mechanism, and 22 (or 51.2 percent) of these ACOs had a higher existing repayment mechanism amount compared to the amount calculated for the new agreement period (determined at the time of renewal application).

Alternatively, to meet the requirements of § 425.204(f), a renewing ACO could establish a new repayment mechanism arrangement to support its participation in its new agreement period, in addition to maintaining its existing repayment mechanism. This option allows an ACO to establish a repayment mechanism to support its new agreement period at a potentially different amount (determined according to § 425.204(f)(4)(ii)) than the amount of the existing arrangement. However, under this approach there is a period of time during which the ACO must maintain multiple repayment mechanisms. The ACO must maintain the repayment mechanism established to support the ACO's previous agreement period until the term of the repayment mechanism arrangement expires, or conditions arise to allow for termination of the repayment mechanism according to § 425.204(f)(6)(iv) (see 83 FR 67933 through 67936). Once the repayment mechanism for the previous agreement period is closed, the ACO would be required to maintain only the repayment mechanism arrangement applicable to its current agreement period. An ACO could use this option to establish a repayment mechanism at a relatively lower amount (if applicable) for its current agreement period, while maintaining and eventually closing-out a repayment mechanism at a relatively higher amount needed for its previous agreement period.

As specified under § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. We require an increase in the repayment mechanism amount if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value. Under § 425.204(f)(4)(iii), an ACO cannot decrease the amount of its repayment mechanism during its agreement period as a result of changes in its composition.

In implementing the revised repayment mechanism rules, we have discovered some unintended consequences. Specifically, under § 425.204(f)(4), a renewing ACO that chooses to retain its higher repayment mechanism for a new agreement period might never be able to reduce its repayment mechanism even after the ACO has paid any shared losses incurred for performance years in the previous agreement period. Moreover, the ACO would have to maintain the higher repayment mechanism amount in future agreement periods unless the ACO opts to establish a new repayment mechanism. We did not intend this result.

More generally, based on our operational experience, many ACOs fully repay shared losses without use of their repayment mechanism arrangement. For example, of the eleven ACOs that owed shared losses for performance year 2018, CMS used the repayment mechanism for one ACO to support recoupment. Considering this experience, which suggests there may be low risk to the Shared Savings Program by allowing lower repayment mechanism amounts, and the potential reduction in burden on ACOs by lower repayment mechanism amounts, we revisited in the CY 2021 PFS proposed rule the policies requiring renewing ACOs to retain higher repayment mechanism amounts when these amounts may no longer be needed to support their continued participation.

b. Revisions

In the CY 2021 PFS proposed rule (85 FR 50248 through 50251), we proposed to establish two policies that would allow certain ACOs to benefit from a lower repayment mechanism amount than would otherwise be required under the current regulations. Under the first proposed policy, a renewing ACO that uses an existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in its new agreement period may reduce its existing repayment mechanism amount if the repayment mechanism amount calculated for the new agreement period is less than the amount of the existing repayment mechanism. The second proposed policy would permit certain ACOs whose agreement periods began July 1, 2019 or January 1, 2020 to elect to reduce the amount of their repayment mechanisms.

Under § 425.204(f)(4)(iv), a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period must maintain its existing repayment mechanism amount if it is higher than the repayment mechanism amount calculated for the new agreement period in accordance with § 425.204(f)(4)(ii). We proposed to discontinue this policy by revising the regulations to specify that we will determine the repayment mechanism amount for such a renewing ACO only according to the methodology currently specified in § 425.204(f)(4)(ii). Under the proposed approach, a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period would be required to have a repayment mechanism amount equal to the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS

[68] Medicare Shared Savings Program, Repayment Mechanism Arrangements, Guidance Document, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf* (herein Repayment Mechanism Arrangements Guidance).

[69] See 76 FR 67937 through 67940 (establishing the requirement for Track 2 ACOs). See 80 FR 32781 through 32785 (adopting the same general requirements for Track 3 ACOs with respect to the repayment mechanism and discussing modifications to reduce burden of the repayment requirements on ACOs).

revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

As specified in the May 8th COVID–19 IFC (85 FR 27574 and 27575), we are forgoing the application cycle for the January 1, 2021 start date. Therefore, the proposed policy for determining the repayment mechanism amount for renewing ACOs would apply with the application cycle for an agreement period starting on January 1, 2022, and in subsequent years.

As discussed in the CY 2021 PFS proposed rule (85 FR 50249), a renewing ACO could still choose to establish a new repayment mechanism arrangement for the amount calculated at the time of the renewal application to support its participation in its new agreement period and maintain its existing repayment mechanism at the previously required amount. Once the conditions arise for termination of the repayment mechanism arrangement supporting the ACO's previous agreement period, according to § 425.204(f)(6)(iv), only the arrangement supporting the ACO's current agreement period would remain.

In the CY 2021 PFS proposed rule (85 FR 50249), we explained our belief that the proposed approach would reduce burden by allowing renewing ACOs that wish to continue use of their existing repayment mechanism to decrease their repayment mechanism amount if a higher amount is not needed to support their new agreement period. As discussed in the CY 2021 PFS proposed rule, the proposal would prevent a higher repayment mechanism amount from following the ACO from one agreement period to the next, as is the case with the current approach. Further, an ACO would no longer need to establish another repayment mechanism for the ACO's new agreement period to ultimately get relief from the higher amount of its existing repayment mechanism arrangement, which the ACO would need to maintain until the conditions arise allowing for termination.

As discussed in the CY 2021 PFS proposed rule, we recognize that the proposal would reduce the amount available to support repayment of shared losses. The typical timing of issuance to ACOs of financial reconciliation, which includes performance results and written notification from CMS of the amount of shared losses owed (if any), is in the summer following the conclusion of the performance year. Renewing ACOs permitted to reduce the amount of their existing repayment mechanism may be notified of shared losses owed for their most recent prior performance year during the application review period and would be in the process of paying shared losses within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)). Further, at the time of renewal application, the ACO would be completing the last performance year of its existing agreement period, and financial reconciliation results for this performance year would likely be available during the summer of the ACO's first performance year of its new agreement period.

However, as discussed in the CY 2021 PFS proposed rule, we believe this risk to CMS noted above is mitigated for a number of reasons. The Shared Savings Program's existing policies require ACOs to pay shared losses, in full, within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)). ACOs have an interest in fully paying the amount of shared losses owed within the 90-day payment window to remain in compliance with the Shared Savings Program's requirements and avoid compliance actions including involuntary termination from the program. CMS may terminate an ACO's participation agreement for reasons including, but not limited to, non-compliance with requirements in part 425 (§ 425.218(b)(1)), such as failure to repay shared losses owed according to the program's regulations and may take pre-termination actions as described in § 425.216. Under § 425.221(b)(2)(ii)(B), an ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. ACOs must also repay shared losses owed to avoid accruing interest on any amount that remains unpaid after the 90-day payment window, and referral of an unpaid debt to the Department of Treasury for collection. Based on our operational experience, nearly all ACOs fully repay shared losses without use of their repayment mechanism arrangement.

Nevertheless, in the CY 2021 PFS proposed rule we considered finalizing a policy that would require a renewing ACO to maintain its existing, higher repayment mechanism amount until the ACO has fully repaid the amount of shared losses determined to be owed for the most recent performance year for which financial reconciliation results are available. Under this approach, for instance, § 425.204(f)(4)(iv) would remain unchanged, and we would amend § 425.204(f)(4)(iii) to add a provision permitting a renewing ACO to reduce the amount of its repayment mechanism.

As discussed in the CY 2021 PFS proposed rule, the Shared Savings Program regulations do not address the opportunity for a re-entering ACO, defined according to § 425.20, to use a repayment mechanism arrangement established to support its participation in an earlier agreement period to also support its participation in a new agreement period. As defined at § 425.20, a ''re-entering ACO'' may or may not be the same legal entity that previously participated in the Shared Savings Program. Specifically, a ''re-entering ACO'' is defined to include the following: (1) An ACO that is the same legal entity as an ACO that previously participated in the program and is applying to participate in the program after a break in participation due to early termination of its participation agreement or the expiration and non-renewal of its participation agreement; and (2) a new legal entity that has never participated in the Shared Savings Program, provided that more than 50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years prior to the agreement start date for the new legal entity.

In the CY 2021 PFS proposed rule, we stated that we were considering finalizing provisions specifying the conditions under which a re-entering ACO may use an existing repayment mechanism arrangement to support its participation in a subsequent agreement period in the Shared Savings Program. Specifically, because a repayment mechanism is valid only with respect to amounts owed by the legal entity to whom or on whose behalf it was issued, we stated that we were considering specifying in the final rule that a re-entering ACO may use its existing repayment mechanism only if it is the same legal entity as the ACO that previously participated in the program. We stated that this option for continued use of an existing repayment mechanism would not be feasible for (and therefore would not be applicable to) a re-entering ACO that is not the same legal entity as the ACO that previously participated in the program and is identified on the repayment mechanism documentation (that is, the proposed policy would not apply to an ACO identified as a re-entering ACO because more than 50 percent of its ACO participants were included on the ACO participant list for a single ACO in

any of the 5 most recent performance years prior to the agreement start date).

We also proposed to establish a second policy that would allow certain ACOs a one-time opportunity to decrease the amount of their repayment mechanisms. Under this proposal, an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism if (1) upon renewal, it elected to use an existing repayment mechanism to establish its ability to repay any shared losses incurred in its new agreement period and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO's new agreement period; and (2) the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount. We noted that the proposal would not be finalized if we finalized our alternate proposal described above to modify § 425.204(f)(4)(iii) to permit a renewing ACO to reduce the amount of its repayment mechanism after the ACO fully repaid the amount of shared losses determined to be owed for the final performance year of its prior agreement period. We explained that the purpose of this second proposal is to let any ACO that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, to decrease its repayment mechanism amount before it seeks to renew its current agreement under the first proposed policy, which if finalized, would otherwise be the earliest opportunity for the ACO to reduce its repayment mechanism amount.

To determine if an ACO that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, is eligible for the one-time opportunity to lower its repayment mechanism amount, we proposed to compare the recalculated amount of the ACO's repayment mechanism based on its certified ACO participant list for performance year 2021, calculated according to § 425.204(f)(4)(iii), to the ACO's existing repayment mechanism amount. If the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount, the ACO would be eligible to decrease the amount of its repayment mechanism to the recalculated amount. Under this approach, we would permit a decrease in the repayment mechanism amount even for relatively small differences in dollar amounts. However, an ACO may wish to maintain the existing amount of its repayment mechanism arrangement, particularly if the cost to the ACO of amending the arrangement outweighs the potential benefit of a nominal decrease in the amount of the repayment mechanism.

We proposed that CMS would notify the ACO in writing that the ACO may elect to decrease the amount of its repayment mechanism. We explained that if we finalized our proposal to allow a one-time opportunity for a repayment mechanism decrease by eligible ACOs that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, we would notify an ACO that it may elect to reduce its repayment mechanism amount after the start of performance year 2021. We also proposed that an ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS would review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

Regarding the timeframe for an ACO to elect to decrease the amount of its repayment mechanism, we indicated that we might require an ACO to submit its election, together with revised repayment mechanism documentation, within 30 days from the date of the written notice from CMS, particularly if prompt election is needed to ensure compliance with other program requirements. For instance, CMS may notify the ACO that it may elect to decrease the amount of its repayment mechanism after using the ACO's existing repayment mechanism to support repayment of shared losses. In this case, prompt notification by the ACO of its election to decrease the amount of its repayment mechanism may be necessary if the ACO seeks to replenish the amount of its repayment mechanism to the permitted lower amount within the 90-day replenishment period according to § 425.204(f)(5). However, we recognized that there may be circumstances that necessitate a longer timeframe.

We proposed to amend § 425.204(f)(4)(iv) by removing the introductory text and specifying in paragraph (f)(4)(iv)(A) the revised methodology for determining the repayment mechanism amount for renewing ACOs that seek to use their existing repayment mechanism to support their continued participation in their new agreement period. We proposed to revise § 425.204(f)(4)(iv)(B) to establish the policy and relevant procedure for allowing eligible ACOs with July 1, 2019, or January 1, 2020 start dates to elect to lower the amount of their repayment mechanism arrangements.

We proposed to amend § 425.204(f)(5), which requires an ACO to replenish the amount of funds available through the repayment mechanism within 90 days of use of the arrangement to repay any portion of shared losses. Specifically, we proposed to specify that the resulting amount available through the repayment mechanism after replenishment must be at least the amount specified by CMS in accordance with § 425.204(f)(4). For example, these revisions would allow an eligible ACO, that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, to replenish the repayment mechanism to the lower amount determined by CMS, according to the proposed approach described in the CY 2021 PFS proposed rule. As proposed, the revision may also be relevant to a renewing ACO that is seeking to use its existing repayment mechanism to support its participation in its new agreement period. Specifically, if the renewing ACO's existing repayment mechanism is used to support payment of shared losses, based on financial reconciliation results available at the time of renewal application, CMS may permit the renewing ACO to replenish the amount of its existing repayment mechanism to the lower amount determined to be applicable for the ACO's new agreement period.

We also proposed technical changes to § 425.204(f)(3)(iv) for clarity. This provision specifies that an ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period, and describes the conditions under which an ACO may use its current repayment mechanism to apply to the new agreement period. For clarity, we proposed to specify under this provision that the duration of the existing repayment mechanism must be revised to comply with § 425.204(f)(6)(ii), and the amount of the repayment mechanism must comply with § 425.204(f)(4).

Further, we proposed that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism. Based on our operational experience, ACOs periodically request to close-out their

existing repayment mechanisms and establish new repayment mechanisms to support their continued participation under a two-sided model. We have typically permitted these requests, under the following circumstances: We first ensure the ACO's new repayment mechanism meets the program's requirements and is fully executed; and then we permit cancellation of the repayment mechanism arrangement(s) being replaced. Further, when reviewing requested modifications to repayment mechanism documentation it is our practice to ensure that all the terms of the repayment mechanism are compliant with the program's policies. Therefore, we proposed to revise the regulations in § 425.204(f)(3)(i) through (iii) to further specify that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism.

We received public comments on the proposals for reducing the amount of repayment mechanisms for eligible ACOs. The following is a summary of the comments we received and our responses.

Comment: Many commenters addressing the program's repayment mechanism policies expressed their support for CMS' proposal to eliminate the requirement that renewing ACOs that wish to continue use of their existing repayment mechanism maintain the higher repayment mechanism amount in their subsequent agreement period, when a lower amount is calculated at the time of renewal application.

One commenter commended CMS for addressing the unintended consequences of ACOs having to maintain a higher-than-required repayment mechanism as they transition to new agreement periods.

One commenter acknowledged CMS' consideration of an alternative that would require renewing ACOs to maintain existing, higher repayment mechanism amounts until they have fully repaid any shared losses owed for the most recent performance year. This commenter stated its belief that other enforcement mechanisms, such as possible pre-termination actions and accruing interest for not repaying shared losses, are sufficient to warrant timely repayment of shared losses.

Response: We are finalizing the proposed changes to determining the amount for repayment mechanisms for renewing ACOs that elect to continue use of their existing repayment mechanism to support their continued participation in a new agreement period, to permit the amount of these arrangements to be reduced.

Under this final policy, specified in revisions to § 425.204(f)(4)(iv)(A), a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period will be required to have a repayment mechanism amount equal to the lesser of the following, as currently specified in § 425.204(f)(4)(ii): (1) 1 Percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. As we described in the CY 2021 PFS proposed rule, and restated in this section of this final rule, these modifications apply to the application cycle for an agreement period starting on January 1, 2022, and in subsequent years.

We are not adopting the alternative we described in the CY 2021 PFS proposed rule, under which we would require a renewing ACO to maintain its existing, higher repayment mechanism amount until the ACO has fully repaid the amount of shared losses determined to be owed for the most recent performance year for which financial reconciliation results are available. Although the policy changes we are finalizing for determining the amount for repayment mechanisms for renewing ACOs may reduce the amount available to CMS to support repayment of shared losses in some cases, we believe the potential burden reduction for ACOs outweighs the risk to CMS. We continue to believe the risk to CMS of reduced repayment amounts for supporting repayment of shared losses is mitigated because the effect of other policies is to encourage compliance with the requirement that ACOs timely repay shared losses in full. As described in the proposed rule and reiterated in this section of the this final rule, ACOs have an interest in fully paying the amount of shared losses owed within the 90-day payment window (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)); timely payment in full allows the ACO to remain in compliance with the Shared Savings Program's requirements and to avoid compliance actions, including involuntary termination from the program and related payment consequences of early termination. Also, timely payment in full of shared losses allows an ACO to avoid accruing interest charges on any unpaid shared losses and referral of an unpaid debt to the Department of Treasury for collection.

Comment: One commenter generally supported the approach that CMS sought comment on for allowing a re-entering ACO identified as the same legal entity as an ACO that previously participated in the program to use that ACO's existing repayment mechanism to support its participation in a new agreement period.

Response: We appreciate the commenter's support for this consideration. We are finalizing this approach by amending § 425.204(f)(4)(iv)(A) to specify that the requirements regarding use of an existing repayment mechanism arrangement to support the ACO's participation in a new agreement period in the Shared Savings Program will apply to both a renewing ACO, and a re-entering ACO that is the same legal entity that previously participated in the Shared Savings Program (either an ACO whose participation agreement expired without having been renewed, or an ACO whose participation agreement was terminated under § 425.218 or § 425.220). Specifically, if a renewing ACO or re-entering ACO that is the same legal entity as an ACO that previously participated in the program wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to at least the amount calculated by CMS in accordance with § 425.204(f)(4)(ii), which is the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

Section 425.204(f)(3)(iv), as amended by this final rule, describes repayment mechanism documentation requirements, and specifies the condition under which a renewing ACO may use its existing repayment mechanism to support its continued participation under a new agreement period. To apply similar requirements to eligible, re-entering ACOs, we are revising the regulations to add a new paragraph (f)(3)(v) to § 425.204 to specify that an ACO that has submitted

an application to the program after a break in participation must submit as part of its application, documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the re-entering ACO, provided that the ACO is the same legal entity as an ACO that previously participated in the program, and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with § 425.204(f)(6)(ii) and the amount of the repayment mechanism complies with § 425.204(f)(4).

We are revising § 425.204(f)(6)(ii), which specifies the required duration for repayment mechanisms for a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period. Specifically, we are revising paragraph (ii) to make it applicable to re-entering ACOs that are the same legal entity as an ACO that previously participated in the program. With these modifications, the provision specifies that a renewing ACO, or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, must amend its existing repayment mechanism to meet either § 425.204(f)(6)(ii)(A) or (B). Respectively, these provisions specify the following:

- The duration of the existing repayment mechanism is extended by an amount of time that covers the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.
- The duration of the existing repayment mechanism is extended, if necessary, to cover a term of at least the first two performance years of the new agreement period and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.

Comment: Commenters expressed support for CMS' proposed approach that provides a one-time opportunity for eligible ACOs that renewed their agreement periods beginning on July 1, 2019 or January 1, 2020, and elected to continue use of their existing repayment mechanism at a higher amount, to decrease their repayment mechanism amount if the recalculated amount for performance year 2021 is less than the existing amount.

Some commenters expressed support for an approach that would allow any ACO the option to decrease its repayment mechanism amount if the recalculated amount for the performance year is less than the current repayment mechanism amount and requested that CMS finalize this policy.

Response: We are finalizing the proposed policy at § 425.204(f)(4)(iv)(B), which grants a one-time opportunity for an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of its repayment mechanism if (1) upon renewal, it elected to use an existing repayment mechanism to establish its ability to repay any shared losses incurred in its new agreement period and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO's new agreement period; and (2) the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount.

At this time, we decline commenters' suggestions to establish a policy to allow for annual repayment mechanism decreases by all two-sided model ACOs, if the recalculated amount for the performance year is lower than their existing repayment mechanism amount. This alternative goes beyond the scope of the modifications we proposed to the program's repayment mechanism requirements. However, we will consider commenters' suggestions and we may revisit this issue in future notice and comment rulemaking.

Comment: One commenter addressing the proposed one-time opportunity for eligible renewing ACOs with a July 1, 2019 and January 1, 2020 start date, to elect to decrease their repayment mechanism amount, urged CMS to consider allowing these ACOs longer than 30 days to submit elections to reduce their repayment mechanism amounts, particularly given the circumstances of COVID–19. However, the commenter did not provide additional details on an alternative timeframe for this election.

Response: We proposed that such elections must be submitted ''by a deadline specified by CMS'' and noted that the deadline might be 30 days from the date of CMS' written notification to the ACO, of its one-time opportunity to decrease its repayment mechanism amount. We appreciate the commenter's concern that an ACO may need more than 30 days to submit its election and the revised repayment mechanism documentation. We are not finalizing a 30-day deadline in regulation text, although such a deadline may ultimately be necessary depending on the circumstances. We continue to believe it is important for ACOs to promptly elect the option for a repayment mechanism decrease, particularly when prompt election is needed to ensure compliance with other program requirements. Consistent with our existing approach to supporting ACOs in meeting repayment mechanism requirements, we anticipate working closing with ACOs to ensure the documentation they provide is sufficient.

We are finalizing the proposed policy by revising § 425.204(f)(4)(iv)(B) to specify that CMS will notify an eligible ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism. We are also finalizing as proposed the policy that the ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

Comment: Some commenters explained that securing a repayment mechanism is a regulatory burden, which is time consuming and costly for ACOs. While some commenters expressed their appreciation for CMS' efforts to minimize burdens associated with the repayment mechanism through the changes proposed with the CY 2021 PFS proposed rule, they also urged CMS to take additional steps to minimize burdens on ACOs associated with repayment mechanism requirements.

Some commenters explained that many ACOs cite the burden and cost of securing a repayment mechanism as reasons not to move to a performance-based risk model. Commenters urged CMS to remove the repayment mechanism requirement when an ACO can prove that it has an investor or financial backer with a demonstrated high credit rating, instead of requiring the ACO to incur the costs of obtaining a repayment mechanism, and thereby direct the ACO's resources away from its core mission of improving patient

care. As suggested by the commenters, financial backers could include outside investors, insurers or hospitals or health systems that are aligned with the ACO and committed to providing financial support, which would be available should losses occur. These commenters noted that this assurance would protect the Medicare Trust Funds in the event the ACO has losses while avoiding the financial inefficiency and regulatory burden of involving outside financial institutions.

These commenters also noted that this alternative approach would also eliminate the need to have a 24-month ''tail period''. Although not specifically stated, we believe commenters are referring to a requirement that ACOs maintain their repayment mechanism for a period of time following the conclusion of the ACO's agreement period. Commenters explained that the additional burden of a 24-month tail period heightens concerns, and increases financial requirements for ACOs. Should CMS maintain requirements for a repayment mechanism, commenters requested that CMS minimize this regulatory and financial burden by removing the requirement for tail period coverage. Commenters indicated this was especially important considering longer agreement periods.

Response: We note that commenters' alternative suggestions, for removing or significantly revising the repayment mechanism requirements, go beyond the scope of the proposals to revise the repayment mechanism requirements discussed in the CY 2021 PFS proposed rule. We decline the commenters' suggestions, including to establish alternative pathways for ACOs to demonstrate their ability to repay shared losses or to shorten the duration for which a repayment mechanism must be available.

We are concerned that commenters' references to a 24-month ''tail period'' requirement suggest a misunderstanding of the existing requirements for the duration of a repayment mechanism. Although in recent rulemaking (83 FR 67933 through 67937) we proposed requiring repayment mechanisms to be in effect for the duration of the ACO's participation in a two-sided model plus 24 months after the conclusion of the agreement period, we ultimately finalized an approach (taking into consideration public comments on our proposals) that requires the repayment mechanism to be available for 12 months following the conclusion of the ACO's agreement period. In brief, as specified under § 425.204(f)(6), the repayment mechanism must be in effect for the duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period, and this can be demonstrated by either of the following: (1) The repayment mechanism covers the entire duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period; or (2) the repayment mechanism covers a term of at least the first 2 performance years in which the ACO is participating under a two-sided model and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the agreement period plus 12 months following the conclusion of the agreement period.

As we have explained in previous rulemaking (see for example, 83 FR 67933, and 80 FR 32783), this tail period must be sufficient to permit CMS to calculate the amount of any shared losses that may be owed by the ACO and to collect this amount from the ACO. This is necessary, in part, because financial reconciliation results are not available until the summer following the conclusion of the performance year, and ACOs have 90 days to make payment in full once they are notified of shared losses based on financial reconciliation (see §§ 425.605(e), 425.606(h), and 425.610(h)). Therefore, we continue to believe that a requirement that an ACO's repayment mechanism be available for 12 months following the conclusion of its agreement period is critical to ensuring the availability of the repayment mechanism to support collection of shared losses that may be owed for the final performance year of the agreement period. As we explained in previous rulemaking, in allowing for a shorter tail period of 12-months, we believed the importance of reducing burden on ACOs outweighed the possible risk to the Trust Funds (83 FR 67934). We would also note that the program's policies under § 425.204(f)(6)(iv) specify the conditions upon which we permit early termination of a repayment mechanism and release of the arrangement's remaining funds to the ACO. This allows us to terminate repayment mechanism arrangements that are no longer needed to support ACOs' participation in the Shared Savings Program, which may free up capital for ACOs.

We appreciate the continued engagement of ACOs and other program stakeholders in suggesting policy alternatives to reducing the burdens of the repayment mechanism requirements on ACOs. We will consider commenters' suggestions, and we may revisit this issue in future notice and comment rulemaking.

As a result of the comments received, we are amending § 425.204(f)(4)(iv) to specify in paragraph (f)(4)(iv)(A) that a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program may use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreements period. That provision also sets forth the revised methodology for determining the repayment mechanism amount for such ACOs. These modifications apply to the application cycle for an agreement period starting on January 1, 2022, and in subsequent years. We are also adding provisions in § 425.204(f)(4)(iv)(B) establishing policies and procedures that allow certain ACOs that renewed for an agreement period beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of their existing repayment mechanisms.

We are adding new paragraph (f)(3)(v) to § 425.204 to allow a re-entering ACO to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, provided that the ACO is the same legal entity as an ACO that previously participated in the Shared Savings Program and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with § 425.204(f)(6)(ii) and the amount of the repayment mechanism complies with § 425.204(f)(4). We are also revising § 425.204(f)(6)(ii) (describing the required duration of the repayment mechanism) to make it applicable to a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, that wishes to use its existing repayment mechanism to support its participation in its new agreement period.

Additionally, we received no public comments on the following proposals, which we are finalizing as proposed:

We are amending § 425.204(f)(5) (regarding the replenishment of funds available through the repayment mechanism) to specify that the resulting amount available through the repayment mechanism after replenishment must be at least the amount specified by CMS in accordance with § 425.204(f)(4).

We are finalizing as proposed certain technical changes to § 425.204(f)(3)(iv). This provision specifies that an ACO that has submitted a request to renew its

participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period, and describes the conditions under which an ACO may use its current repayment mechanism to apply to the new agreement period. For clarity, we are finalizing our proposed modification to specify under this provision that the duration of the existing repayment mechanism must be revised to comply with § 425.204(f)(6)(ii), and the amount of the repayment mechanism must comply with § 425.204(f)(4).

Lastly, we are finalizing the proposal to revise § 425.204(f)(3)(i) through (iii) to further specify that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism.

4. Applicability of Policies to Track 1+ Model ACOs

In the CY 2021 PFS proposed rule (85 FR 50251 and 50252), we provided a comprehensive discussion of the applicability of the proposed policies specified in section III.G and section III.I of the proposed rule to Track 1+ Model ACOs. We explained which of the proposed policies would become applicable to Track 1+ Model ACOs either through revisions to existing Shared Savings Program regulations that currently apply to Track 1+ Model ACOs or through the addition of new provisions that would apply to Track 1+ ACOs in the same way that they apply to ACOs in Track 1. However, we also explained the circumstances under which certain changes in policies would become applicable through an amendment to the ACO's Track 1+ Model Participation Agreement.

We received no public comments directly addressing the applicability of the policies proposed in the CY 2021 PFS proposed rule to Track 1+ Model ACOs. However, a few commenters expressed their support for applying the voluntary 1-year extension, for ACOs whose agreement periods would otherwise expire on December 31, 2020, to Track 1+ Model ACOs. Although this policy was established in the May 8th COVID–19 IFC (85 FR 27574 and 27575, see also 85 FR 27586 and 27587), we explained in the CY 2021 PFS proposed rule (85 FR 50251) that Track 1+ Model ACOs, among other ACOs whose agreement periods would otherwise expire on December 31, 2020, were eligible to voluntarily elect a 1-year extension of their agreement period for a fourth performance year from January 1, 2021, to December 31, 2021.

However, we believe it would be helpful to summarize how the policies we are finalizing in sections III.G and III.I of this final rule apply to Track 1+ Model ACOs. Unless specified otherwise, the changes to the program's regulations finalized in this final rule that are applicable to Shared Savings Program ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or the ENHANCED track have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, any changes to those regulations that are finalized in this final rule will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or the ENHANCED track. For example, the following final policies will apply to Track 1+ Model ACOs:

- The application of the APP to determine the quality performance of Shared Savings Program ACOs (section III.G.1.c. of this final rule).
- The revisions to the Shared Savings Program quality performance standard. Specifically, under the modified approach we are finalizing, the quality performance standard for Track 1+ Model ACOs will be set at a quality score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, for performance year 2021 (section III.G.1.c. of this final rule).
- The modifications to the regulations under § 425.604(c) specifying the circumstances under which a Track 1 ACO will qualify to receive a shared savings payment (section III.G.1.d. of this final rule).
- The modifications to the regulations under § 425.604(d) governing the determination of the final sharing rate for Track 1 ACOs (section III.G.1.d. of this final rule).
- The modifications to § 425.316 to allow CMS to identify ACOs that are not meeting the revised quality performance standard finalized this final rule, and to require these ACOs to take actions to address their poor quality performance or face termination of their Shared Savings Program participation agreement (section III.G.1.e. of this final rule).
- The modifications to the policies governing the audit and validation of data used to determine the ACO's quality performance. Specifically, under the new provision of the regulations at § 425.510(c), CMS retains the right to audit and validate the quality data reported by an ACO according to § 414.1390 (section III.G.1.f. of this final rule).
- The new provision of the regulations at § 425.512(b) to address the effect of extreme and uncontrollable circumstances on ACOs' quality performance for performance year 2021 and subsequent performance years (section III.G.1.g. of this final rule).
- The revisions to the definition of primary care services used in beneficiary assignment. The revised definition is applicable to Track 1+ Model ACOs for the performance year starting on January 1, 2021, and we will adjust the Track 1+ ACO's historical benchmark to reflect these policies (section III.G.2 of this final rule).
- The changes to the CAHPS for ACOs reporting requirements for performance year 2020 (section III.I.1 of this final rule).

5. Medicare Shared Savings Program Provisions From the May 8th COVID–19 IFC

In the May 8th COVID–19 IFC, we noted that, as of January 1, 2020, there were 517 Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) serving approximately 11.2 million Medicare FFS beneficiaries across the country: 37 percent of ACOs (192 of 517) were participating under two-sided shared savings and shared losses models; and 160 ACOs had agreements ending December 31, 2020, and would be required to renew under the BASIC track or ENHANCED track to continue in the Shared Savings Program, including 20 ACOs participating in the Medicare ACO Track 1+ Model (Track 1+ Model).

In the May 8th COVID–19 IFC, we expressed our belief that the COVID–19 pandemic, and the resulting PHE as defined in § 400.200, have created a lack of predictability for many ACOs regarding the impact of expenditure and utilization changes on historical benchmarks and performance year expenditures, and for those under performance-based risk, the potential liability for shared losses, as well as disrupting population health activities, as clinicians, care coordinators and financial and other resources are diverted to address immediate acute care needs. We explained that ACOs and other program stakeholders have advocated for CMS to modify Shared Savings Program policies to address the

impact of the COVID–19 pandemic including to:

• Adjust the methodology for determining shared savings and shared losses, such as by: Reducing or eliminating liability for ACOs under performance-based risk for shared losses for PY 2020; not sharing savings or losses with ACOs for PY 2020; or adjusting program calculations to address the impact of COVID–19 on benchmark and PY expenditures, particularly for calendar year 2020.

• Eliminate or extend the deadline for ACOs to voluntarily terminate from the program without being financially reconciled for PY 2020, which under § 425.221(b)(2)(ii)(A) is June 30, 2020, with notification 30 days prior (no later than June 1).

• Maintain or ''freeze'' ACOs in their current participation options so that ACOs otherwise required to renew their participation for a new agreement period starting on January 1, 2021, to continue their participation in the Shared Savings Program, are not burdened with meeting application deadlines, and forgo the requirement that ACOs participating in the BASIC track's glide path advance to the next level for PY 2021.

• Account for changes in billing and care patterns in determining beneficiary assignment.

In the May 8th COVID–19 IFC (85 FR 27574), we explained that ACOs and other program stakeholders had indicated that there was an urgent need to address these concerns because ACOs needed to make participation decisions for PY 2020 and PY 2021 and may choose to terminate their participation in the Shared Savings Program on or before June 30th, rather than face the potential of pro-rated losses for PY 2020 if the PHE for COVID–19 does not extend for the entire year or the program's policies do not adequately mitigate liability for shared losses.

We expressed our belief that it is vital to the stability of the Shared Savings Program to encourage continued participation by ACOs by adjusting program policies as necessary to address the impact of the COVID–19 pandemic, including by offering certain flexibilities in program participation options to currently participating ACOs and addressing potential distortions in expenditures resulting from the pandemic to ensure that ACOs are treated equitably regardless of the degree to which their assigned beneficiary populations are affected by the pandemic. We explained that the changes we were making in the May 8th COVID–19 IFC would help to ensure a more equitable comparison between ACOs' expenditures for PY 2020 and ACOs' updated historical benchmarks and that ACOs are not rewarded or penalized for having higher/lower COVID–19 spread in their patient populations which, in turn, would help to protect ACOs from owing excessive shared losses and the Medicare Trust Funds from paying out windfall shared savings. As described in the May 8th COVID–19 IFC (85 FR 27573 through 27587), we modified Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by one year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021; (2) clarify the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19; (3) adjust program calculations to mitigate the impact of COVID–19 on ACOs; and (4) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also addressed how these adjustments to program policies would apply to ACOs participating in the Track 1+ Model.

In response to the May 8th COVID–19 IFC, CMS received 57 timely pieces of correspondence addressing Shared Savings Program policies. We thank commenters for their thoughtful consideration of the modifications to and clarifications of Shared Savings Program policies included in the May 8th COVID–19 IFC. Within section III.G.5. of this final rule, we summarize and respond to public comments, and discuss our final policies after taking into consideration the public comments we received on the May 8th COVID–19 IFC. Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the policies addressed in the May 8th COVID–19 IFC, and will not be addressed in this section of this final rule.

Comment: Generally, some commenters expressed their appreciation for CMS' call for a renewed national commitment to value-based care.[70] These commenters generally underscored the importance of value-based healthcare as a stabilizing force during the COVID–19 pandemic. A few commenters explained that alternative payment models like the Shared Savings Program have enabled healthcare providers and ACOs to more effectively adapt to the challenges of delivering care during the PHE compared to their counterparts that are more reliant on reimbursement under traditional FFS. Another commenter described value-based healthcare initiatives, of which the Shared Savings Program is Medicare's flagship program, as proving to be ''a port in the storm during COVID–19'' offering both infrastructure and expertise unavailable in traditional FFS and predictable revenue during unpredictable times. One commenter explained that ACOs represent a viable path for a further step away from volume-focused medicine and its problematic incentives.

Some commenters specifically described ACOs' efforts to meet the Shared Savings Program's goals and provide for the health and safety of their patients during the COVID–19 pandemic, as in any other performance year. Some commenters described ACOs' agility in responding to disruptions in their routine monitoring of and care for patients, for example by rapidly deploying, or implementing, strategies to respond to the COVID–19 pandemic, including coordinating with local healthcare providers, expanding telehealth services, and diverting care coordinators to help manage patient outcomes. One commenter described ACOs' efforts to ''double down on existing risk targeting and care coordination efforts'' which helped support vulnerable patients to shelter safely in their homes with needed medications, food and other essentials. As another commenter described, many program participants have transitioned care to virtual platforms and/or provided care on porches or in parking lots or other outdoor settings as appropriate. This commenter explained that program participants are also working to establish long-term plans for triaging and treating patients with chronic conditions who are currently not seeking care because of the COVID–19 pandemic.

Some commenters detailed the challenges ACOs face in implementing their business operations within the pandemic. As described by one

[70] Although not specifically described in the May 8th COVID–19 IFC, CMS' commitment to value-based care has been announced in recent publications. See for example, Verma S. New CMS Payment Model Flexibilities for COVID–19. *Health Affairs.* June 3, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200602.80889/full/.* See also, CMS Press Release, ''Trump Administration Issues Call to Action Based on New Data Detailing COVID–19 Impacts on Medicare Beneficiaries'' (June 22, 2020), available at *https://www.cms.gov/newsroom/press-releases/trump-administration-issues-call-action-based-new-data-detailing-covid-19-impacts-medicare.*

commenter, ACOs are procuring the personal protective equipment (PPE) needed to treat patients in person, applying for loans, keeping track of new guidance and policy changes, and making financial decisions related to their business. As another illustration, some commenters explained that while their commitment to value-based care was unwavering, the financial strains and uncertainty of the COVID–19 pandemic presents a difficult choice for ACOs' future.

Response: As we described in a recent publication,[71] we recognize beneficiaries and healthcare providers have been facing unprecedented challenges due the COVID–19 pandemic. The pandemic has underscored the need for a resilient healthcare system where reimbursement is not tied to the volume of services provided, but rather to value-based incentives to keep patients healthy. The Shared Savings Program is one of the country's largest initiatives on value-based care, equipping healthcare providers with the flexibility to innovate and focus on health outcomes that can help them respond to the pandemic. We appreciate ACOs' continued commitment to meeting the goals of the Shared Savings Program while facing challenges in caring for Medicare FFS beneficiaries and operating their organizations during the COVID–19 pandemic.

a. Application Cycle for January 1, 2021 Start Date and Extension of Agreement Periods Expiring on December 31, 2020

As we explained in the May 8th COVID–19 IFC (85 FR 27574), a renewing ACO is defined as an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is an ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program, or an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program (see § 425.20). Section 425.224 specifies application procedures for a renewing ACO applying to enter a new participation agreement with CMS for participation in the Shared Savings Program. In the May 8th COVID–19 IFC, we explained that we were seeking to reduce operational burden for ACOs and their healthcare providers while they respond to the serious health threats posed by the spread of the COVID–19. We described that we had received feedback from ACO stakeholders requesting that CMS delay the Shared Savings Program application cycle for a January 1, 2021 start date (occurring in CY 2020), since they had reassigned staff and care coordinators to respond to the current pandemic. Stakeholders expressed concern about focusing resources on applying to the Shared Savings Program rather than on patient care during the PHE for COVID–19. Additionally, stakeholders expressed uncertainty over their continued participation in the Shared Savings Program in 2021 given the lack of predictability of the impact of COVID–19 on the expenditures used to establish an ACO's historical benchmark.

In response to stakeholder feedback, in the May 8th COVID–19 IFC (85 FR 27574), we announced we were forgoing the application cycle for a January 1, 2021 start date (herein referred to as the 2021 application cycle). We explained our belief that it is appropriate to forgo the 2021 application cycle as the PHE for COVID–19 continues because this would allow ACOs and their ACO providers/suppliers currently participating in the Shared Savings Program to continue focusing on treating patients during the pandemic. We explained there were 160 Medicare Shared Savings Program ACO participation agreements that would end on December 31, 2020, including 20 ACOs participating in the Track 1+ Model. These ACOs would have been required to apply to renew their participation agreement to continue participating in the Shared Savings Program effective January 1, 2021. To reduce burden and allow these ACOs to continue participating in the program without a 2021 application cycle, we allowed ACOs that entered a first or second agreement period with a start date of January 1, 2018, the opportunity to elect to extend their agreement period for an optional fourth performance year. The fourth performance year would span 12 months from January 1, 2021, to December 31, 2021. This election to extend the agreement period would be voluntary and an ACO could choose not to make this election, and therefore, conclude its participation in the program with the expiration of its current agreement period on December 31, 2020. Under this approach, eligible ACOs would be able to remain under their existing historical benchmark for an additional year, which would increase stability and predictability given the potential impact of the pandemic on beneficiary expenditures under FFS Medicare and help provide greater certainty for ACOs making determinations regarding their future participation in the Shared Savings Program.

Additionally, we explained that by forgoing the 2021 application cycle for new applicants, CY 2020 will not serve as benchmark year 3 for a cohort of ACOs that would otherwise be January 1, 2021 starters (85 FR 27574 and 27575). An ACO's historical benchmark is determined based on the 3 most recent years prior to the start of its agreement period. For ACOs in a first agreement period, benchmark year 3 is given the highest weight of the 3 benchmark years and, because we expected CY 2020 to be an anomalous year, we explained our belief that it could be disadvantageous to include CY 2020 expenditures as the third benchmark year for this cohort of ACOs. Cancelling the 2021 application cycle would provide us with additional time to consider and develop approaches to further mitigate the role of 2020 as a benchmark year given the unusual expenditure and utilization trends likely to result from the pandemic.

As established in the May 8th COVID–19 IFC (85 FR 27575), the ACO's voluntary election to extend its agreement period must be made in the form and manner and by a deadline established by CMS, and an ACO executive who has the authority to legally bind the ACO must certify the election. We noted that this optional 12-month agreement period extension was a one-time exception for all ACOs with agreements expiring on December 31, 2020; it would not be available to other ACOs or to future program entrants. Eligible ACOs were able to notify CMS of their decision to elect to extend their agreement starting June 18, 2020 and ending September 22, 2020.

We explained that under the existing provision at § 425.210(a), the ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. In the case of an ACO that elects to extend its agreement period pursuant to the May 8th COVID–19 IFC, we indicated that we would consider the ACO to be in compliance with § 425.210(a) if it notifies these parties that it will continue to participate in the program for an additional year. Further, under § 425.210(b), all contracts or arrangements between or among the

[71] Verma S. 2019 Medicare Shared Savings Program ACO Performance: Lower Costs And Promising Results Under 'Pathways To Success.' *Health Affairs.* September 14, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200914.598838/full/.*

ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program's regulations, including, but not limited to, those specified in the participation agreement with CMS (see also § 425.116(a)(3) (as to agreements with ACO participants) and (b)(3) (as to agreements with ACO providers/suppliers)). Thus, as we explained in the May 8th COVID–19 IFC (85 FR 27575), an ACO that elects to extend its participation agreement pursuant to the policy established by the IFC must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities during PY 2021 to comply with the program's requirements through December 31, 2021. We noted that to remain in compliance with § 425.116, an ACO may need to extend the duration of its agreements with ACO participants and ACO providers/suppliers.

We revised § 425.200(b)(3)(ii) to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, to elect to extend their agreement period for an optional fourth performance year (85 FR 27575). We explained that while we were forgoing the application cycle for ACOs to apply to enter an agreement period beginning on January 1, 2021, eligible, currently participating ACOs would be able to apply for a SNF 3-day rule waiver (§ 425.612(a)(1)(i)), apply to establish a beneficiary incentive program (§ 425.304(c)(2)), modify ACO participant (§ 425.118(b)) and/or SNF affiliate lists (§ 425.612(a)(1)(i)(B)), and elect to change their assignment methodology (§ 425.226(a)(1)) for PY 2021 (85 FR 27575). Also, an ACO participating under the BASIC track's glide path could still elect to transition to a higher level of risk and potential reward within the BASIC track's glide path other than the level of risk and potential reward that the ACO would be automatically transitioned to for PY 2021, absent the ACO's election to maintain its current participation level for one year as described in section II.L.2. of the May 8th COVID–19 IFC (85 FR 27575 and 27576). For example, an ACO participating in BASIC track Level B in PY 2020 could still elect to transition to BASIC track level D or E in PY 2021.

We received public comments on the approach we established in the May 8th COVID–19 IFC under which ACOs whose participation agreements were scheduled to expire on December 31, 2020, could elect to extend their agreement period for an optional fourth performance year. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' decision to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, the opportunity to extend their agreement period for an optional fourth performance year, spanning 12 months, from January 1, 2021, to December 31, 2021.

Response: We appreciate commenters' support for providing eligible ACOs the opportunity to extend their agreement period for an optional fourth performance year. Eligible ACOs had until September 22, 2020, to notify us of their election to extend their participation agreement. Of the Shared Savings Program ACOs with an agreement set to expire on December 31, 2020, 89 percent have elected to extend their agreement period for an additional performance year.

Comment: Most commenters urged CMS to reconsider its decision to forgo the Shared Savings Program 2021 application cycle, and a few commenters noted that the decision to cancel the application cycle would impede participation in Alternative Payment Models (APMs) during 2021. Several organizations commented on CMS' commitment to reducing administrative burdens on applicants, given the strain on resources as a result of the PHE for COVID–19, expressing appreciation for the added flexibility, but strongly believed that the decision whether it is too burdensome to apply to enter a new agreement period should be left up to the ACO. A number of commenters suggested that CMS reverse its decision to forgo a 2021 application cycle, and allow (for example) agreement period start dates of either April 1, 2021, or July 1, 2021. In urging CMS to allow for an agreement period start date in 2021, one commenter suggested an alternative approach to identifying the benchmark years, which included using 2017, 2018, and 2019 as benchmark years, and thereby avoiding the use of 2020 as a benchmark year.

A few commenters requested that CMS consider making opportunities available for Track 1 ACOs whose agreement periods expire on December 31, 2020, to elect to transition to a two-sided model for performance year 2021, or to enter a new agreement period under a two-sided model beginning on January 1, 2021, such as by allowing these ACOs to enter the ENHANCED track or the BASIC track's glide path.

Response: While we appreciate commenters' support for an agreement period start date in 2021, we decline at this time to establish such an option. At the time of this final rule, we do not believe that we have enough time to develop policies for a mid-year start date in 2021, because the program's rules and regulations are generally based on the calendar year from January 1 through December 31, and significant modifications would be needed to accommodate a start date other than January 1 during 2021. Such regulatory changes would require notice and comment rulemaking, and we would then require time to implement an application process. We would also need to allow ACOs enough time to review the regulation and apply for the program; allow for CMS' review of applications, including vetting of ACO participants through program integrity and law enforcement screening; allow for both parties to sign participation agreements; and allow time for CMS to deliver assignment list reports prior to the start date of the agreement period. Further, there would be complexities with establishing a mid-year start date in 2021, which would require additional analysis and policy development, followed by further consideration of those policies by prospective applicants and existing ACOs. These complexities, as described in previous rulemaking (see, for example, 83 FR 67944 through 67967), include policies for determining the ACO's assigned population, determining shared savings and shared losses, and quality reporting for a short performance year, among other factors. A further consideration would be the use of 2020 as benchmark year 3 in establishing historical benchmarks for agreement periods starting in 2021. While we appreciate the commenter's suggestion that we use alternative benchmark years in order to avoid using 2020 as a benchmark year, we decline at this time to make any additional modifications to the Shared Savings Program's benchmarking methodology. As discussed in section III.G.5.d.(2) of this final rule, we anticipate continuing to monitor and evaluate the impact of the PHE for COVID–19 on Medicare FFS expenditures and Shared Savings Program payment calculations, to help inform potential future policy modifications to the Shared Savings Program. We believe it is premature to undertake such policy modifications at the time of this final rule.

We appreciate commenters' support for APM participation through participation in a Shared Savings Program ACO. We note that existing

ACOs had the opportunity to make ACO participant list modifications that will be effective for performance year 2021, which we believe provided an opportunity for additional TINs, and thereby the providers and suppliers that have assigned their billing rights to these TINs, to begin participating in the Shared Savings Program, or for existing ACO participant TINs to participate under a different Shared Savings Program ACO.

We decline at this time to adopt the commenters' suggestions to allow ACOs that elect the 1-year extension of their participation agreement to also elect a different track of participation for performance year 2021 or to allow these ACOs to enter a new agreement period under a two-sided model, beginning on January 1, 2021, such as allowing Track 1 ACOs to elect to transition to performance-based risk on the BASIC track's glide path or to enter the ENHANCED track. The approach we established in the May 8th COVID–19 IFC contemplates an extension of the ACO's existing agreement period, not entry into a new agreement period, which would include (for instance) rebasing the ACO's historical benchmark. Such an approach would also raise the same concerns as allowing ACOs to enter the Shared Savings Program for a start date in 2021, in particular around the use of 2020 as a benchmark year. Similarly, the approach adopted in the May 8th COVID–19 IFC does not contemplate that ACOs would be permitted to elect to participate under a different track during the optional fourth performance year under their current participation agreement. We encourage ACOs interested in transitioning to performance-based risk, or entering higher levels of risk and potential reward, to apply to do so at the next opportunity, which will be the application cycle for an agreement period beginning on January 1, 2022.

After considering the comments received, we are finalizing without modification the revisions to the provision at § 425.200(b)(3)(ii) to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, to elect to extend their agreement period for an optional fourth performance year.

b. Allow BASIC Track ACOs To Elect To Maintain Their Participation Level for One Year

We finalized a redesign of Shared Savings Program's participation options in the final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'', which appeared in the **Federal Register** on December 31, 2018 (83 FR 67816). We finalized the BASIC track, added as a new provision at § 425.605, which includes an option for eligible ACOs to begin participation under a one-sided model and incrementally phase-in risk (calculated based on ACO participant revenue and capped at a percentage of the ACO's updated benchmark) and potential reward over the course of a single agreement period, an approach referred to as the glide path (83 FR 67841). The glide path includes five levels: A one-sided model available only for the first 2 consecutive performance years of a 5-year agreement period, each year of which is identified as a separate level (Levels A and B); and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Levels C, D, and E). ACOs are automatically advanced along the progression of risk/reward levels at the start of each participation year, over the course of a 5-year agreement period, unless the ACO elects to advance more quickly, until ACOs reach the BASIC track's maximum level of risk/reward (Level E) (83 FR 67844). For ACOs that entered the BASIC track's glide path for an agreement period beginning on July 1, 2019, the progression through the levels of risk and potential reward spans 6 performance years, including the ACO's first performance year from July 1, 2019, through December 31, 2019; these ACOs were not automatically advanced to the next risk/reward level at the start of PY 2020 (§ 425.200(b)(4)(ii), (c)(3); § 425.600(a)(4)(i)(B)(*2*)(*i*)).

As explained in the May 8th COVID–19 IFC (85 FR 27575 and 27576), stakeholders have expressed concerns that due to the unpredictable impact of COVID–19 during PY 2020, and the uncertainty as to their ability to secure a repayment mechanism for PY 2021, ACOs are uncertain they will continue participating in the program if they are automatically transitioned to downside risk or a higher level of downside risk in PY 2021. Specifically, stakeholders requested we ''freeze,'' or forgo the automatic advancement of BASIC track ACOs and allow them to remain at their current level of participation for PY 2021. Additionally, per § 425.204(f)(3)(iii), an ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to a two-sided model of the BASIC track, including Level C, Level D, or Level E. We noted our concern whether some ACOs, particularly those that would automatically transition to Level C of the BASIC track, would be able to establish a repayment mechanism prior to the start of PY 2021 because the source of capital to cover potential losses may be uncertain for some ACOs given the resource intensity of responding to the pandemic. We noted that 136 ACOs participating under Level B of the BASIC track were scheduled to automatically advance to Level C on January 1, 2021. As discussed in the May 8th COVID–19 IFC (85 FR 27576), some stakeholders indicated that they may be unable to secure a letter of credit, while other stakeholders indicated that their discretionary funds were fully committed to responding to the PHE for COVID–19.

We also expressed concern that some of the care coordination processes ACOs have been developing may be interrupted by the pandemic. For example, ACOs may have reallocated funding and staff resources to respond to the PHE for COVID–19, thereby temporarily disrupting their ability to implement redesigned care processes that would support their transition to risk. We agreed with stakeholders that most ACOs did not know the impact that COVID–19 would have on their expenditures or beneficiary population and the potential for losses under risk arrangements. Therefore, we permitted ACOs participating in the BASIC track's glide path to elect to maintain their current level of participation under the BASIC track for PY 2021. During the summer of 2020, applicable ACOs were able to elect to remain in the same level of the BASIC track's glide path that the ACO entered for PY 2020. For PY 2022, an ACO that elected this advancement deferral option will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2022 if it had advanced automatically to the next level for PY 2021 (unless the ACO elects to advance more quickly before the start of PY 2022). For example, if an ACO participating in the BASIC track, Level B, in PY 2020 elected to maintain its current level of participation for PY 2021, it will participate under Level B for PY 2021 and then will automatically advance to Level D for PY 2022, since the ACO would have moved automatically to Level C for PY 2021 under current program rules, absent this

change. The ACO could also elect to advance more quickly by opting to move to Level E instead of Level D for PY 2022, in which case the ACO would participate under Level E for the remainder of its agreement period.

In the May 8th COVID–19 IFC, we redesignated § 425.600(a)(4)(i)(B)(*2*)(*iii*) as § 425.600(a)(4)(i)(B)(*2*)(*iv*) and added a new § 425.600(a)(4)(i)(B)(*2*)(*iii*) to allow ACOs currently participating in the BASIC track's glide path to elect to maintain their current participation level for PY 2021.

We received public comments on the advancement deferral option we established in the May 8th COVID–19 IFC. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for CMS' decision to permit ACOs participating in the BASIC track's glide path the option to voluntarily elect to maintain their current participation level under the BASIC track for PY 2021.

Response: We appreciate commenters' support for allowing ACOs participating in the BASIC track the opportunity to elect to remain in the same level of the BASIC track's glide path for PY 2021 as they entered for PY 2020.

Comment: Several commenters urged CMS to reconsider its decision to move ACOs to the level of risk they would have been in for 2022, absent the freeze. Commenters noted that skipping a level would be challenging under normal circumstances. However, under the extenuating circumstances of the PHE for COVID–19, they believed this requirement would not allow them the opportunity to focus on recovering financially and would take attention away from providing the best patient care, serving only to drive ACOs from the Shared Savings Program. Some commenters suggested that CMS allow ACOs to freeze their current risk level as proposed, but then resume the glide path in performance year 2022 at the risk level they would have been automatically advanced to for performance year 2021, absent their election to freeze their participation level for that performance year.

Response: Of the BASIC track ACOs that participated in PY 2020, 77 percent of these ACOs began the agreement period that includes that performance year as renewing or re-entering ACOs, as defined at § 425.20. These ACOs all have prior experience participating in the Shared Savings Program; some of these ACOs have continuously participated in the program since 2012. We believe that entering an agreement period under the BASIC track's glide path suggests that these ACOs should already have been taking steps to prepare to enter performance-based risk and to progress to higher levels of risk and potential reward in order to continue their participation in the Shared Savings Program. We believe that by enabling these ACOs to gain additional experience in meeting the Shared Savings Program's goals within the context of the PHE for COVID–19 by allowing them to maintain their current participation level for performance year 2021, these ACOs will be further prepared to progress to higher levels of risk and potential reward within the BASIC track's glide path in PY 2022. Additionally, we note that some ACOs are currently ready to take on increasing levels of performance-based risk, as 9 percent of the ACOs participating in the BASIC track's glide path in PY 2020 have elected to advance along the glide path more quickly than required. Therefore, at this time, we decline commenters' suggestions to further slow ACOs' progression along the BASIC track's glide path by allowing ACOs that have elected to maintain their position on the glide path for PY 2021 to resume their progression at the level they would have entered for PY 2021, absent the freeze.

Comment: Many commenters suggested that CMS allow additional participation options under which ACOs would be protected from shared losses (such as options to allow ACOs to select no downside risk), with some commenters suggesting that these alternatives include reduced (lower) shared savings rates. For example, commenters suggested that we allow ACOs to elect the level of risk/reward currently available under the one-sided models of the BASIC track, under which ACOs take on no downside risk and share in savings at a rate of up to 40 percent, based on quality performance. While some commenters suggested making this alternative available for PY 2020, other commenters' suggestions for such an option seemed to be more open-ended, without specifying which cohorts of ACOs should be eligible or for how long this option should continue to be available. A number of commenters conveyed their belief that, absent this protection, and given the uncertainty around the end date of the PHE for COVID–19, ACOs may choose to leave the program rather than be at risk for shared losses under a two-sided model. One commenter explained that, at a minimum, CMS should allow ACOs to opt for lower shared savings rates in exchange for reduced downside risk, given that, due to the PHE for COVID–19, circumstances have drastically changed since ACOs performed their original cost-benefit calculations and signed their participation agreements. Another commenter explained that many clinicians are concerned about their ability to assume financial risk during this unprecedented time. Allowing ACOs the option to be protected from shared losses, along with existing policies in the Shared Savings Program to address extreme and uncontrollable circumstances, would support participants as they weigh continued participation in the program. Finally, some commenters conveyed their belief that it is very important to protect ACOs that are harmed by the PHE for COVID–19 from shared losses, and that it is also critical to allow eligible ACOs to still earn shared savings for PY 2020. These commenters explained that ACOs make significant investments to enhance quality, address chronic disease, and improve patient care, and shared savings are instrumental to continuing those initiatives.

Response: At this time, we do not believe it is necessary to provide alternative participation options for future performance years, and note that any new participation options would need to be established through additional notice and comment rulemaking. We believe a combination of policies will encourage continued participation by ACOs under the Shared Savings Program's existing financial models, in particular: The program's extreme and uncontrollable circumstances policies for mitigating shared losses, which will reduce ACOs' liability for losses for months covered by the PHE for COVID–19, including any applicable months within performance year 2021 (refer to section III.G.5.c of this final rule); the adjustment to program calculations for episodes of care for treatment of COVID–19, triggered by inpatient services (as discussed in section III.G.5.d.(2) of this final rule); and the policies to address the effect of extreme and uncontrollable circumstances on ACO quality performance (as discussed in section III.G.1.g and section III.I of this final rule).

At the time of this final rule, the PHE for COVID–19 has been renewed with an effective date of October 23, 2020, and, unless terminated early, will remain in effect for 90 days from the effective date. Under the Shared Savings Program's extreme and uncontrollable circumstances policies for mitigating shared losses (described in section III.G.5.c of this final rule), shared losses will be mitigated for all ACOs

participating in a performance-based risk track, including: Track 2, the ENHANCED track, Levels C, D and E of the BASIC track, and the Track 1+ Model, for the duration of the PHE for COVID–19 as specified in § 400.200, which started in January 2020. If the PHE covers the full year (January through December 2020) any shared losses an ACO incurs for performance year 2020 would be reduced completely, and the ACO would not owe any shared losses. Under the Shared Savings Program's existing policies, ACOs will continue to be eligible to share in savings if they meet the criteria for doing so, as specified in the regulations at §§ 425.604(c), 425.605(c), 425.606(c), 425.610(c). As described in section III.G.5.d. of this final rule, we will adjust certain Shared Savings Program calculations, including the determination of benchmark and performance year expenditures, to remove payment amounts for episodes of care for treatment of COVID–19, triggered by an inpatient service. These adjustments will help protect CMS and ACOs against distortions in expenditures resulting from the COVID–19 pandemic that could affect shared savings and shared losses calculations. We believe these policies mitigate commenters' concerns about the availability of shared savings and the risk of shared losses under the existing participation options.

After considering the comments received, we are finalizing without modification the redesignation of § 425.600(a)(4)(i)(B)(*2*)(*iii*) as § 425.600(a)(4)(i)(B)(*2*)(*iv*) and the addition of a new § 425.600(a)(4)(i)(B)(*2*)(*iii*) to allow ACOs currently participating in the BASIC track's glide path to elect to maintain their current participation level for PY 2021.

c. Applicability of Extreme and Uncontrollable Circumstances Policies to the PHE for COVID–19

In the May 8th COVID–19 IFC (85 FR 27576 and 27577), we clarified, for purposes of the Shared Savings Program, that the months affected by an extreme and uncontrollable circumstance would begin with January 2020, consistent with the PHE for COVID–19 determined to exist nationwide as of January 27, 2020, by the Secretary on January 31, 2020, and continue through the end of the PHE, as defined in § 400.200, which includes any subsequent renewals.

We explained in the May 8th COVID–19 IFC (85 FR 27577) that catastrophic events outside the ACO's control could also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO's benchmark in the subsequent agreement period. We explained these factors could jeopardize the ACO's ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program.

Therefore, as explained in the May 8th COVID–19 IFC (85 FR 27577), we believed it was important to make clear that, under the existing extreme and uncontrollable circumstances policies for the Shared Savings Program, the timeframe for the extreme and uncontrollable circumstance of the COVID–19 pandemic for purposes of mitigating shared losses will extend for the duration of the PHE for COVID–19 as specified in § 400.200, which begins in January 2020. We explained that if the PHE for COVID–19 extends through all of CY 2020, all shared losses for PY 2020 will be mitigated for all ACOs participating in a performance-based risk track: Including Track 2, the ENHANCED track, Levels C, D and E of the BASIC track, and the Track 1+ Model. At the time of the May 8th COVID–19 IFC, the PHE for COVID–19 had covered 4 months (January through April 2020) meaning any shared losses an ACO incurred for PY 2020 would be reduced by at least one-third. We explained that if the PHE for COVID–19 extends for a large portion, if not all of the year, the existing extreme and uncontrollable circumstances policy under the Shared Savings Program would mitigate a significant portion of, if not all, shared losses an ACO may owe for PY 2020. For example, if the PHE for COVID–19 were to cover 6 months (January through June 2020) any shared losses an ACO incurs for PY 2020 would be reduced by one-half; if the PHE for COVID–19 were to cover 9 months (January through September 2020) any shared losses an ACO incurs for PY 2020 would be reduced by three-fourths; and if the PHE for COVID–19 were to cover the full year (January through December 2020) any shared losses an ACO incurs for PY 2020 would be reduced completely, and the ACO would not owe any shared losses.

We received public comments on our clarification of the applicability of the extreme and uncontrollable circumstances policies to the COVID–19 pandemic for purposes of mitigating shared losses under the Shared Savings Program. The following is a summary of the comments we received and our responses.

Comment: Commenters discussing this topic generally welcomed the clarification that the PHE for COVID–19 constituted an extreme and uncontrollable circumstance for purposes of mitigating shared losses, beginning in January 2020. While one commenter expressed support for the approach specified in the May 8th COVID–19 IFC, under which the extreme and uncontrollable circumstances policy would mitigate shared losses based on the duration of the PHE, many other commenters addressing this issue tended to express concern that mitigation of shared losses would cease with the end of the PHE. In particular, commenters expressed concern about the extent to which this approach would mitigate shared losses in light of the uncertainty over the length of the PHE (at the time of the comment period, which closed on July 7, 2020, the PHE was known to extend through July 25, 2020) and the potential for ''early termination'' of the PHE. Several commenters suggested that CMS extend the extreme and uncontrollable circumstances policy for mitigating shared losses for the duration of PY 2020. Several commenters suggested that CMS extend the policy to any performance year that starts during the PHE. One commenter questioned how CMS would adjust the methodology to account for variability in impact if the Secretary were to amend the PHE from a nationwide declaration to a regional one. More generally, one commenter explained the Shared Savings Program extreme and uncontrollable circumstances policy had previously been used to address natural phenomena (such as hurricanes or wildfires), which may be short-lived, and noted the COVID–19 global pandemic is different due to the uncertainty over when it may end.

One commenter, in expressing support for the approach to mitigating shared losses under the extreme and uncontrollable circumstances policy described in the May 8th COVID–19 IFC, also expressed their support for the continued ability of ACOs to share in savings generated from their diligent investments in the health and safety of their patient populations during the COVID–19 crisis. This echoed some other commenters' suggestions, underscoring the importance of shared savings payments in helping to address the financial strains placed on ACOs by COVID–19.

Response: We appreciate the commenters' support for the clarification regarding the duration of the PHE for COVID–19 and the applicability of the extreme and uncontrollable circumstances policy to mitigate shared losses for PY 2020.

In December 2017, we issued an interim final rule with comment period entitled ''Medicare Program: Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' (hereinafter referred to as the ''December 2017 IFC''), which appeared in the December 26, 2017 **Federal Register** (82 FR 60912 through 60919). In the December 2017 IFC (82 FR 60914), we aligned the extreme and uncontrollable circumstances policies under the Shared Savings Program with the policy established under the Quality Payment Program. Specifically, the Shared Savings Program extreme and uncontrollable circumstances policies apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. We use the determination of an extreme and uncontrollable circumstance under the Quality Payment Program, including the identification of affected geographic areas and applicable time periods, for purposes of determining the applicability of the extreme and uncontrollable circumstances policies with respect to both financial performance and quality reporting under the Shared Savings Program. We extended the extreme and uncontrollable circumstances policies finalized for PY 2017, including the alignment with the Quality Payment Program, to PY 2018 and subsequent years in the CY 2019 PFS final rule (83 FR 59969 through 59973). The Medicare Shared Savings Program and Quality Payment Program interact closely. All of the tracks of the Shared Savings Program are considered MIPS APMs, and Track 2, the ENHANCED track, and Level E of the BASIC track are also designated Advanced APMs. The two programs have several overlapping goals, including achieving better health for individuals, better population health, and lowering growth in expenditures. Because of these interactions and overlaps, we continue to believe that it is appropriate to use the same time periods and geographic areas as the Quality Payment Program when implementing the Shared Savings Program extreme and uncontrollable circumstances policies. We further clarify that if the PHE for COVID–19 transitions from a national PHE to a regional PHE, the Shared Savings Program will continue to apply the extreme and uncontrollable circumstances policy in the impacted geographic areas. At the time of this final rule, the PHE for COVID–19 has been renewed for another 90 days, with an effective date of October 23, 2020. Unless the PHE for COVID–19 is terminated early, all shared losses for performance year 2020 would be mitigated.

d. Adjustments to Shared Savings Program Calculations To Address the COVID–19 Pandemic

(1) Background

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate, and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act.

Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Title XVIII and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model. The authority under section 1899(i)(3) of the Act to use other payment models includes authority to adopt alternatives to the benchmarking methodology set forth in section 1899(d)(1)(B)(ii) of the Act, and alternatives to the methodology for determining expenditures for each performance year as set forth in section 1899(d)(1)(B)(i) of the Act. As discussed in earlier rulemaking, we have used our authority under section 1899(i)(3) of the Act to adopt alternative policies to the provisions of section 1899(d)(1)(B) of the Act for updating the historical benchmark,[72] and calculating performance year expenditures.[73] We have also used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models,[74] and to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during PY 2017 and subsequent performance years.[75]

Under the Shared Savings Program, providers and suppliers continue to bill for services furnished to Medicare beneficiaries and receive FFS payments under traditional Medicare. CMS uses payment amounts for Parts A and B FFS claims for a variety of Shared Savings Program operations, which include: Calculations under the benchmarking methodology; determining an ACO's eligibility for shared savings and liability for shared losses for each performance year under the program's financial models as specified in the regulations in subpart G; determining an ACO's eligibility for certain participation options as set forth in § 425.600(d); and calculating the amount of the repayment mechanism required for ACOs participating in a two-sided model according to § 425.204(f)(4). These operations typically require the determination of expenditures for Parts A and B services under the original Medicare FFS program for a specified population of Medicare FFS beneficiaries or the Medicare Parts A and B FFS revenue of ACO participants. We note that the Medicare FFS beneficiary population for which expenditures are determined may

[72] Such as using only assignable beneficiaries instead of all Medicare FFS beneficiaries in calculating the benchmark update based on national FFS expenditures (81 FR 37986 through 37989), calculating the benchmark update using factors based on regional FFS expenditures (81 FR 37977 through 37981), and calculating the benchmark update using a blend of national and regional expenditure growth rates (83 FR 68027 through 68030).

[73] Such as excluding indirect medical education and disproportionate share hospital payments from ACO performance year expenditures (76 FR 67921 through 67922), and determining shared savings and shared losses for the 6-month performance years (or performance period) in 2019 using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year or performance period (83 FR 59949 through 59951, 83 FR 67950 through 67956).

[74] See earlier rulemaking establishing two-sided models: Track 2 (76 FR 67904 through 67909), Track 3 (subsequently renamed the ENHANCED track) (80 FR 32771 through 32772), and the BASIC track (83 FR 67834 through 67841).

[75] See earlier rulemaking establishing policies for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances (82 FR 60916 through 60917, 83 FR 59974 through 59977).

differ depending on the specific program operation being performed and may reflect expenditures for the ACO's assigned beneficiaries, assignable beneficiaries as defined in § 425.20, or all Medicare FFS beneficiaries. The applicable Medicare FFS beneficiary population is specified in the regulations governing each program operation.

(2) Removing Payment Amounts for Episodes of Care for Treatment of COVID–19 From Shared Savings Program Expenditure and Revenue Calculations

Section 3710 of the CARES Act amended section 1886(d)(4)(C) of the Act to specify that for discharges occurring during the emergency period described in section 1135(g)(1)(B) of the Act, in the case of a discharge of an individual diagnosed with COVID–19, the Secretary shall increase the weighting factor that would otherwise apply to the diagnosis-related group (DRG) to which the discharge is assigned by 20 percent. Further, the Secretary shall identify a discharge of such an individual through the use of diagnosis codes, condition codes, or other such means as may be necessary. In this section of this final rule, we refer to this increase in the weighting factor for DRGs as the ''DRG adjustment.''

In the May 8th COVID–19 IFC (85 FR 27578), we explained our expectation that the localized nature of infections (for example, rapid outbreaks in individual nursing facilities (NFs)) and the unanticipated increase in expenditures, along with the increased flexibilities that have been implemented to allow healthcare providers to identify and treat COVID–19 patients would affect the level of Medicare Parts A and B expenditures during 2020, both for the Medicare FFS beneficiaries assigned to ACOs and for the other populations of Medicare FFS beneficiaries whose expenditures are considered in performing calculations under the Shared Savings Program. The localized nature of outbreaks and the increased utilization of acute care occurring in PY 2020 and the associated higher costs are not reflected in ACOs' historical benchmarks, which are determined under § 425.601(b), § 425.602(b), or § 425.603(d), as applicable, based on Parts A and B expenditures for the beneficiaries who would have been assigned to that ACO during the three benchmark years. For some ACOs, the higher costs associated with COVID–19 may not be fully accounted for (or in other cases may be over-represented) by the retrospective application of the update factor to the benchmark at the time of financial reconciliation. In addition, the prospective CMS–HCC risk scores, which are used to adjust the historical benchmark each performance year for changes in severity and case mix (refer to §§ 425.601(a)(10), 425.602(a)(9), and 425.603(c)(10); and §§ 425.604(a)(1), 425.605(a)(1), 425.606(a)(1), and 425.610(a)(1), (2)), would not be expected to meaningfully adjust for such variability because they are prospective, and therefore, use diagnoses from 2019 to predict costs in 2020.

Furthermore, including the increased expenditures related to treatment of COVID–19 in calculations of ACO benchmarks for which CY 2020 is a benchmark year could lead to higher than anticipated future historical benchmarks unnecessarily advantaging some ACOs once the prevalence of COVID–19 in the population begins to decrease, and the corresponding reduction in expenditures is reflected in performance year expenditures. In contrast, we explained our belief that the methodology used to update benchmarks would appropriately reflect any reduction in expenditures due to a cumulative yearlong decline in elective services and the deferral of other services as a result of regionally-uniform responses by beneficiaries and providers/suppliers to directives issued at federal, state, and local levels. Therefore, the retrospective application of the historical benchmark update (which for PY 2020 is either an update factor based on national growth rates, regional growth rates, or a blend of national and regional growth rates, depending on the start date of the ACO's agreement period) would be expected to reasonably account for lower utilization of services by non-COVID–19 patients and prevent windfall shared savings payments to ACOs for PY 2020.

In the May 8th COVID–19 IFC (85 FR 27579), we explained that including payment amounts for treatment of acute care for COVID–19 in calculations for which calendar year 2020 is used as a reference year could also distort repayment mechanism estimates and the identification of high and low revenue ACOs and influence ACO participation options. For example, ACOs could potentially be misclassified as either high revenue or low revenue, due to changes in expenditures arising from the COVID–19 pandemic, and either moved more quickly to higher levels of risk and reward if they are identified as high revenue ACOs or allowed additional time under a one-sided model (if eligible) or in relatively lower levels of performance-based risk if they are identified as low revenue ACOs.

We explained our belief, at the time of the May 8th COVID–19 IFC, that ACOs currently participating in a performance-based risk track urgently needed to understand how we would address any distortions in expenditures resulting from the COVID–19 pandemic. Under the Shared Savings Program's regulations at § 425.221(b)(2)(ii)(A), an ACO under a two-sided model that voluntarily terminates its participation agreement with an effective date of termination after June 30th of the applicable performance year is liable for a pro-rated share of any shared losses determined for that performance year. Under § 425.220(a) of the regulations, ACOs are required to provide CMS at least 30 days' advance notice of their decision to voluntarily terminate from the program. As a result, ACOs participating under a two-sided model would need to provide notice to CMS no later than June 1, 2020, to avoid liability for a pro-rated share of any shared losses that may be determined for PY 2020. We explained that ACOs and other program stakeholders had expressed concern that ACOs would need to make participation decisions in advance of this June 1, 2020 deadline, and might choose to terminate their participation in the Shared Savings Program on or before June 30th, rather than risk owing pro-rated shared losses for PY 2020. We noted that the Shared Savings Program's extreme and uncontrollable circumstances policy would mitigate shared losses for these ACOs. However, given the uncertainty surrounding the duration of the PHE for COVID–19, at the time of the May 8th COVID–19 IFC, specifically, whether the PHE would cover the entire CY 2020, and absent information regarding the steps that CMS intended to take to address the high costs associated with COVID–19 patients, we acknowledged that many risk-based ACOs might elect to leave the program by June 30, 2020, to avoid the risk of owing shared losses.

We explained our belief that it was necessary to revise the policies governing Shared Savings Program financial calculations, as well as certain other program operations, to mitigate the impact of unanticipated increases in expenditures related to the treatment of COVID–19. Given that ACOs in two-sided models had very limited time (less than 2 months at the time of development of the May 8th COVID–19 IFC) to decide whether to continue their participation in the program or voluntarily terminate without being liable for shared losses, we identified an urgent need to establish policies to

address the impact of COVID–19 on Shared Savings Program financial calculations. More generally, we explained that ACOs engage in care coordination and population-based activities for Medicare FFS beneficiaries, as they work towards achieving the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries. We noted the urgency in taking steps to avoid adversely impacting ACOs, many of which rapidly adapted to the circumstances of the PHE for COVID–19 in order to continue to coordinate care and deliver value-based care to Medicare FFS beneficiaries and meet program goals. We expressed our concern that, in the absence of policies that adjust certain program calculations to remove payment amounts for episodes of care for treatment of COVID–19, ACOs might elect to leave the Shared Savings Program, setting back progress made in transitioning the healthcare system from volume-based to value-based payment. Therefore, as described in the May 8th COVID–19 IFC, we found good cause to waive prior notice and comment rulemaking to establish policies to mitigate the impact of the COVID–19 pandemic on Shared Savings Program financial calculations.

We revised our policies under the Shared Savings Program to exclude from Shared Savings Program calculations all Parts A and B FFS payment amounts for an episode of care for treatment of COVID–19, triggered by an inpatient service during the PHE for COVID–19, and as specified on Parts A and B claims with dates of service during the episode. We relied on our authority under section 1899(d)(1)(B)(ii) of the Act to adjust benchmark expenditures for other factors in order to remove COVID–19-related expenditures from the determination of benchmark expenditures. We also exercised our authority under section 1899(i)(3) of the Act to apply this adjustment to certain other program calculations, including the determination of performance year expenditures.

We explained that an approach that makes the triggering event for this adjustment the beneficiary's receipt of inpatient care for COVID–19, would identify the most acutely ill patients and, as a result, those patients with the highest-costs associated with acute care treatment. In contrast, we explained our belief that treatment for COVID–19 that does not result in an inpatient admission does not raise the same level of concern in terms of generating unexpected performance year expenditures that are not appropriately reflected in the benchmark calculations. As William Bleser and colleagues described,[76] citing a recent actuarial estimate of COVID–19 costs,[77] outpatient care was approximately 10 percent of the cost of hospital care, indicating that hospital costs are the dominant source of overall costs for treatment of COVID–19. We believed these findings supported an approach that bases the exclusion of expenditures on the triggering event of an inpatient admission for treatment of COVID–19. Furthermore, we explained that some outpatient care would occur close-in-time to an eventual inpatient admission and following discharge. Under the approach we established, where an episode of care includes the month of admission and the month following discharge, outpatient care occurring within the timeframe for an episode of care would also be excluded from financial calculations.

Accordingly, under the approach we adopted in the May 8th COVID–19 IFC, we indicated we would identify an episode of care triggered by an inpatient service for treatment of COVID–19, based on either: (1) Discharges for inpatient services eligible for the 20 percent DRG adjustment under section 1886(d)(4)(C) of the Act; or (2) discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the IPPS, such as CAHs, when the date of admission occurs within the PHE for COVID–19 as defined in § 400.200.

For example, we indicated that we would identify discharges of an individual diagnosed with COVID–19 using the following ICD–10–CM codes:

- B97.29 (Other coronavirus as the cause of diseases classified elsewhere) for discharges occurring on or after January 27, 2020, and on or before March 31, 2020.
- U07.1 (COVID–19) for discharges occurring on or after April 1, 2020, through the duration of the PHE for COVID–19, as defined in § 400.200.[78]

We explained that episodes of care for treatment of COVID–19 may be triggered by an inpatient admission for acute care either at an acute care hospital or other healthcare facility, which may include temporary expansion sites, Medicare-enrolled ASCs providing hospital services to help address the urgent need to increase hospital capacity to treat COVID–19 patients, CAHs, and potentially other types of providers.[79]

We defined the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date. We explained that this approach to measuring the length of the episode of care in units of months aligns with the Shared Savings Program's methodology for calculating benchmark year and performance year expenditures by performing separate calculations for each of four Medicare enrollment types (ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid). As described in the final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations'', which appeared in the June 10, 2016 **Federal Register** (81 FR 37950), we account for circumstances where a beneficiary is enrolled in a Medicare enrollment type for only a fraction of a year (see 81 FR 37981). Specifically, we determine the number of months that an assigned beneficiary is enrolled in each specific Medicare enrollment type and divide by 12. Summing these fractions across all assigned beneficiaries in each Medicare enrollment type results in total person years for the beneficiaries assigned to the ACO. Benchmark and performance year expenditures for each enrollment type are calculated on a per capita basis. The numerator of the per capita expenditure calculation for a particular enrollment type reflects the total Parts A and B expenditures incurred by all assigned beneficiaries in that enrollment type during the year, with adjustments made to exclude indirect medical education and disproportionate share hospital payments, to include individually beneficiary identifiable

[76] Bleser WK, et al. Maintaining Progress Toward Accountable Care And Payment Reform During A Pandemic, Part 1: Utilization And Financial Impact. *Health Affairs*. April 14, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200410.281882/full/*.

[77] COVERED California. The Potential National Health Cost Impacts to Consumers, Employers and Insurers Due to the Coronavirus (COVID–19). Policy/Actuarial Brief (March 22, 2020). Available at *https://hbex.coveredca.com/data-research/library/COVID-19-NationalCost-Impacts03-21-20.pdf*.

[78] *See* for example, MLN Matters, ''New Waivers for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the CARES Act'' (April 15, 2020), available at *https://www.cms.gov/files/document/se20015.pdf*.

[79] *See* CMS fact sheet, ''Hospitals: CMS Flexibilities to Fight COVID–19'', dated March 30, 2020, available at *https://www.cms.gov/files/document/covid-hospitals.pdf*, describing flexibilities CMS specified for hospitals for the provision of inpatient care to fight COVID–19.

final payments made under a demonstration, pilot or time limited program, and to truncate beneficiary expenditures to minimize variation from catastrophically large claims. The denominator reflects total person years for the enrollment type.

In addition to excluding Parts A and B payment amounts with dates of service in the months associated with an episode of care for treatment of COVID–19, we explained that we would also exclude the affected months from total person years used in per capita expenditure calculations. For example, if a beneficiary had an episode of care for COVID–19 that lasted for 2 months, but was otherwise enrolled as an aged/non-dual eligible beneficiary for the full calendar PY, we would exclude their Parts A and B expenditures for those 2 months and compute their fraction of the year enrolled in the aged/non-dual eligible population as 10/12. Adjusting both expenditures and person years ensures that both the numerator and denominator used to calculate per capita expenditures are based on the same number of months of beneficiary experience and allow ACOs to be treated equitably regardless of the degree to which their assigned beneficiary population is affected by the pandemic.

We expressed our belief that this approach would provide for a more equitable comparison between an ACO's performance year expenditures and its historical benchmark and help to ensure that ACOs are not rewarded or penalized for having higher/lower COVID–19 spread in their assigned beneficiary populations which, in turn, would help to protect CMS against paying out windfall shared savings and ACOs in two-sided models from owing excessive shared losses. Further, we described our belief that the retrospective application of the historical benchmark update, which is calculated based on factors that reflect actual expenditure and utilization changes nationally and regionally, other than expenditures for episodes of care for treatment of COVID–19, would also help to mitigate the potential for windfall savings due to potentially lower utilization of services not related to treatment for COVID–19.

In the May 8th COVID–19 IFC, we established an adjustment to the following Shared Savings Program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes, including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.
- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including the following calculations:

++ Determining average county FFS expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.603(e) for purposes of calculating the ACO's regional FFS expenditures. For example, for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, we will use county FFS expenditures from which we exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19 in determining the regional component of the blended national and regional growth rates used to (1) Trend forward benchmark year 1 and benchmark year 2 expenditures to benchmark year 3 according to § 425.601(a)(5)(iii), and (2) to update the benchmark according to § 425.601(b)(3). Further, we will use county expenditures from which we exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19 to update the ACO's rebased historical benchmark, according to § 425.603(d) for ACOs in a second agreement period beginning on or before January 1, 2019, based on regional growth rates in Medicare FFS expenditures.

++ Determining the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries for purposes of the following: (1) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures (§§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4)), and performance year expenditures (§§ 425.604(a)(4), 425.605(a)(3), 425.606(a)(4), 425.610(a)(4)); and (2) truncating expenditures for assignable beneficiaries in each county for purposes of determining county FFS expenditures according to §§ 425.601(c)(3) and 425.603(e)(3).

++ Determining 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.601(a)(8)(ii)(C).

++ Determining the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries, for purposes of updating the ACO's historical benchmark according to § 425.602(b)(2).

++ Determining national growth rates that are used as part of the blended growth rates used to trend forward benchmark year 1 and benchmark year 2 expenditures to benchmark year 3 according to § 425.601(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to § 425.601(b)(2).

- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).
- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility for participation options according to § 425.600(d).
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

We noted that there are certain payments related to the PHE for COVID–19 that fall outside of Medicare FFS Parts A and B claims, and by virtue of this fact, these payments would not be utilized under the Shared Savings Program methodology for determining beneficiary expenditures. For example, we would not account for recoupment of accelerated or advance payments,[80] which occurs outside of the FFS claims processing system. This is because the underlying Parts A and B claims used in Shared Savings Program expenditure calculations would continue to reflect the amount the providers/suppliers are eligible to be paid, although that payment may be subject to offset for repayment of accelerated or advance payments. Further, Shared Savings Program expenditure calculations also would not need to account for lump sum payments made to hospitals and other healthcare providers through the

[80] *See* CMS, ''Fact Sheet: Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID–19 Emergency,'' available at *https://www.cms.gov/files/document/accelerated-and-advanced-payments-fact-sheet.pdf.*

CARES Act Provider Relief Fund,[81] that occur outside of Parts A and B claims. We explained that we would continue to capture Medicare FFS Parts A and B payments to providers/suppliers, including hospitals and other healthcare providers receiving these funds, in Shared Savings Program calculations.

We explained that it was necessary to use our authority under section 1899(i)(3) of the Act to remove payment amounts for episodes of care for treatment of COVID–19 from the following calculations: (1) Performance year expenditures; (2) updates to the historical benchmark; and (3) ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track. To use our authority under section 1899(i)(3) of the Act to adopt an alternative payment methodology to remove payment amounts for episodes of care for treatment of COVID–19 from these calculations, we had to determine that the alternative payment methodology would improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. We explained our belief that these adjustments, which remove payment amounts for episodes of care for treatment of COVID–19 from the specified Shared Savings Program calculations, would capture and remove from program calculations expenditures that are outside of an ACO's control, but that could significantly affect the ACO's performance under the program. In particular, we believed that failing to remove this spending would likely create highly variable savings and loss results for individual ACOs that happen to have over-representation or under-representation of COVID–19 hospitalizations in their assigned beneficiary populations.

Based on our assessment of the impacts of this policy for purposes of the May 8th COVID–19 IFC (85 FR 27615 and 27616), we did not believe excluding payment amounts for episodes of care for treatment of COVID–19 from the specified calculations would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we believed these adjustments to our payment calculations to remove expenditures associated with treatment of COVID–19, in combination with the optional 1-year extension for ACOs whose current agreement periods expire on December 31, 2020 (as discussed in section II.L.1. of the May 8th COVID–19 IFC, 85 FR 27574 and 27575), and the option for ACOs in the BASIC track's glide path to elect to maintain their current level of risk and reward for PY 2021 (as discussed in section II.L.2. of the May 8 CthOVID–19 IFC, 85 FR 27575 and 27576) would provide greater certainty for currently participating ACOs. As a result, we expected that these policies would support ACOs' continued participation in the Shared Savings Program in the face of significant uncertainty arising from the disruptions due to the COVID–19 pandemic and the resulting PHE. We believed that, in turn, these organizations would continue working towards meeting the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

Based on these considerations, and our assessment of the impacts of these adjustments in the May 8th COVID–19 IFC (85 FR 27615 and 27616), we believed adjusting certain Shared Savings Program calculations to remove payment amounts for episodes of care for treatment of COVID–19 from the calculation of performance year expenditures, updates to the historical benchmark, and ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track, would meet the requirements for use of our authority under section 1899(i)(3) of the Act.

In the May 8th COVID–19 IFC, we also acknowledged that some trends and longer lasting effects of the COVID–19 pandemic were challenging to anticipate at the time of development of the IFC, and we would continue to evaluate the ongoing impact of the COVID–19 pandemic to determine whether additional rulemaking would be necessary to further adjust Shared Savings Program policies. For example, we noted that it was unclear whether the COVID–19 pandemic may have longer-term effects into 2021, such as through rebounding elective procedure costs in 2021 following potentially sustained reductions in 2020 or to what extent the reduction in these procedures may persist. Further, we anticipated learning more about the potential longer-term implications of the COVID–19 pandemic on Medicare beneficiaries' health and the healthcare system.

We added a new provision at § 425.611 to describe the adjustments CMS makes to Shared Savings Program calculations to address the impact of the COVID–19 pandemic.

We received comments on the approach to adjusting program calculations to mitigate the financial impact of the COVID–19 pandemic on ACOs that we established in the May 8th COVID–19 IFC. The following is a summary of the comments we received and our responses.

Comment: Many commenters that commented on the adjustments to Shared Savings Program calculations generally supported removal of Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment COVID–19 from those calculations. Some commenters specified their support in particular for application of this adjustment to the determination of benchmark expenditures, truncation factors, and performance year expenditures. Some commenters specified their support for adjustments to remove Parts A and B FFS payment amounts associated with episodes of care for treatment of COVID–19 from revenue calculations used for purposes of determining loss recoupment limits, as well as identifying whether an ACO is a high revenue ACO or low revenue ACO, and determining the ACO's eligibility for certain participation options. One commenter also stated its support for adjustment of repayment mechanism amount calculations, or recalculations of these amounts, to remove episodes of care for treatment of COVID–19.

A few commenters agreed that these adjustments would lead to more equitable comparisons between ACOs' performance year expenditures and their benchmarks, and assist in ensuring ACOs are not rewarded or penalized for being more or less impacted by COVID–19. One commenter stated that these adjustments would address potential distortions in the determination of shared savings and shared losses for the months impacted by COVID–19. One commenter, addressing the adjustment to remove payment amounts for episodes of care from benchmark expenditures, indicated that the approach adopted in the May 8th COVID–19 IFC addressed uncertainty related to COVID–19. One commenter explained that this adjustment will help to protect ACOs from circumstances out of their control at a time of immense financial risk and will provide them with important protections that will allow them to continue participating in the Shared Savings Program.

Response: We appreciate the support of commenters for the approach we established in the May 8th COVID–19 IFC to adjust certain Shared Savings

[81] *See* HHS website, CARES Act Provider Relief Fund, at *https://www.hhs.gov/provider-relief/index.html.*

Program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19, as described previously in this section of this final rule and specified in § 425.611.

Comment: A few commenters stated that the existing benchmarking methodology, and in particular the retrospective application of the benchmark update that reflects Medicare cost trends in the ACO's regional service area, was resilient to the impacts of COVID–19, suggesting that CMS' concern over windfall shared savings may be overstated. Some commenters indicated that the effects of the adjustment of benchmark and performance year expenditures for episodes of care are uncertain and could be either beneficial or disadvantageous to ACOs when they are compared to the national or regional expenditure trends that factor into their benchmarks.

One commenter explained that for ACOs in markets hard hit by COVID–19, the benchmark update will reflect those additional costs, and ACOs will be judged by whether they reduced costs relative to other healthcare providers that are subject to the same market conditions. Another commenter, describing concerns about the Shared Savings Program's blended national and regional growth rates used to trend and update the benchmark, explained that relying too heavily on a national trend (for ACOs whose assigned beneficiaries represent a large share of the assignable beneficiaries in their regional service area) is especially problematic during a pandemic with regional variation as it ignores important local market dynamics that differ across the country. This commenter explained that ACOs in COVID–19 hot spots will likely have higher costs than the overall nation. Therefore, according to this commenter, using the national trend as part of the benchmarking methodology would be detrimental and unfair to these ACOs as it is not reflective of the pandemic's effect on costs in their region.

Several commenters indicated that if COVID–19 causes Medicare costs to drop in a market, the benchmark update will reflect those lower costs, and ACOs in those markets would have to lower costs even more to generate shared savings. One commenter expressed concern over whether the retrospective application of the benchmark update would reasonably account for lower utilization of services by non-COVID–19 patients. Some commenters viewed this dynamic as potentially unfair for ACOs engaged in efforts to reduce inappropriate utilization or over utilization compared to existing high spending ACOs.

A few commenters urged CMS to undertake further analysis of the impact of COVID–19 on ACO benchmarks. For example, commenters urged CMS to evaluate whether the factors based on regional FFS expenditures in program calculations sufficiently account for irregular distribution of COVID–19 impacts across different regions and even within regions, wide variation in expenses, divergent practice patterns, and the unprecedented change in beneficiary behavior.

Response: We continue to believe the adjustments to Shared Savings Program calculations for episodes of care for treatment of COVID–19 are an important and necessary safeguard to help to protect ACOs from owing excessive shared losses, and the Medicare Trust Funds from paying out windfall shared savings.

We believe one significant function of the adjustment for episodes of care for treatment of COVID–19 is to protect ACOs from higher-cost COVID–19 expenditures that may be variable and therefore hard to predict. At the time of this final rule, based on initial analysis of data through Q2 of 2020 used in developing Shared Savings Program reports, most ACOs appear to have experienced a relatively small impact from the adjustments that remove episodes of care for treatment of COVID–19 from performance year expenditures. We observed a 1 percent or less median difference between adjusted and non-adjusted Q2 2020 expenditure values for ACOs relative to non-adjusted Q1 2020 expenditure values. We also observed, for example, that ACOs with higher impacts as a result of removing episodes of care for treatment of COVID–19 also tended to have higher proportions of older beneficiaries and beneficiaries who are dually eligible for Medicare and Medicaid, which is consistent with observations about COVID–19 trends in the Medicare population.[82]

Currently, ACOs participating in the Shared Savings Program are subject to several different benchmarking methodologies that vary in the degree to which trends in national or regional FFS expenditures are used in calculating the annual update to the ACO's historical benchmark, which is applied retrospectively following the conclusion of the performance year. Depending on the ACO's agreement period start date, an ACO's benchmark will be updated for performance year 2020 according to one of the following approaches (as applicable): Blended national and regional expenditure growth rates (§ 425.601(b)); growth rates in risk-adjusted FFS expenditures among assignable beneficiaries in the ACO's regional service area (§ 425.603(d)); or the absolute amount of projected growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, for assignable beneficiaries (§ 425.602(b)).

As we have described in earlier rulemaking (see for example, 76 FR 67925 through 67927, 81 FR 38004, and 83 FR 68026), benchmark updates could have mixed effects on ACOs, depending on changes in utilization and expenditure patterns within the assignable beneficiary population used to calculate these factors in the performance year compared to benchmark year 3. We agree with commenters that significant changes in expenditures and utilization within the Medicare FFS population during a performance year, including as a result of COVID–19, have the potential to result in variances in the benchmark update.

Early analysis indicates that the adjustment to remove episodes of care for treatment of COVID–19 may mitigate commenters' concerns that ACOs may be disadvantaged by the benchmark update methodology under the circumstances of the pandemic. When modeling the impact of removing episodes of care for treatment of COVID–19 from trend factors for ACOs with the highest rates of COVID–19 diagnoses, these ACOs' regional trends appear lower than national trends, suggesting that ACOs in ''hot spots'' appear to benefit from the blend. Additionally, after removing episodes of care for treatment of COVID–19, the distribution of ACO expenditure trends and regional expenditure trends between Q1 and Q2 2020 are fairly similar. This suggests ACOs and their regions are likely experiencing the same localized effects as a result of the pandemic and that use of regional factors in updating ACOs' benchmarks should help to protect against windfall

[82] These observations appear consistent with other recent observations about COVID–19 trends in the Medicare population. See for example, CMS Press Release, ''Trump Administration Issues Call to Action Based on New Data Detailing COVID–19 Impacts on Medicare Beneficiaries'' (June 22, 2020), available at *https://www.cms.gov/newsroom/press-releases/trump-administration-issues-call-action-based-new-data-detailing-covid-19-impacts-medicare* (Describing a snapshot of data on the Medicare population, for the period between January 1 and May 16, 2020. Observations included the following: Older Americans and those with chronic health conditions are at the highest risk for COVID–19; and dual eligible beneficiaries had the second highest rates of hospitalization among the Medicare population).

savings without unduly disadvantaging ACOs.

However, at the time of this final rule, we believe it is still too soon to identify the full extent of the impact of COVID–19 on regional and national FFS expenditures. We anticipate better understanding these impacts as we analyze data for the remaining quarters of 2020 and the performance year 2020 results (determined after the conclusion of the performance year). We agree with the comments indicating the importance of ongoing evaluation of factors used in program calculations. We anticipate continuing to monitor the program's calculations, and in particular, the factors used to trend and update the benchmark, to understand the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic.

More generally, as described in the recently released results for performance years (or the performance period) in 2019, we are still gaining experience with the benchmarking methodology established in the Shared Savings Program December 2018 final rule (83 FR 68005 through 68030) and specified in § 425.601, which includes the use of blended national and regional trend and update factors. However, we believe the 2019 Shared Savings Program results are a promising indicator that this benchmarking methodology provides appropriate incentives for Shared Savings Program ACOs.[83]

Comment: One commenter sought clarification of the retrospective application of the historical benchmark update discussed in the May 8th COVID–19 IFC.

Response: The Shared Savings Program's benchmarking methodology is specified in regulations in part 425, subpart G (titled Shared Savings and Losses), and in particular within §§ 425.601, 425.602, 425.603, and 425.611. For detailed information on how CMS calculates the financial benchmark that is used to assess annual financial performance, we also refer readers to the Shared Savings and Losses and Assignment Methodology Specifications, available on the Shared Savings Program ''Program Guidance & Specifications'' web page, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.*

At the time of financial reconciliation for each performance year, which follows the conclusion of the performance year, CMS calculates and applies an update to the ACO's historical benchmark to reflect the rate of growth in expenditures since benchmark year 3. The methodology for calculating the update to the benchmark is determined based on the ACO's agreement period start date as specified in the regulations at §§ 425.601(b), 425.603(d), and 425.602(b), as applicable.

The update to the benchmark is calculated and applied retrospectively after the conclusion of the performance year. CMS provides each ACO with the calculated updated benchmark amount in the financial reconciliation report for the performance year. ACOs reconciled for participation in performance year 2020 will receive a financial reconciliation report in the summer of 2021, which will include the ACO's updated historical benchmark, for which the update will have been determined after removing expenditures for episodes of care for treatment of COVID–19 as specified in § 425.611.

Comment: One commenter expressed its belief that removing spending for COVID–19 is unlikely to produce a reasonable estimate of what spending would have been without COVID–19. The commenter stated that this approach may, for example, underestimate the services patients with certain chronic conditions (who are disproportionately affected by COVID–19) would have used had they not been admitted for inpatient hospital services for COVID–19. The commenter indicated that the approach for adjusting expenditures for episodes of care for treatment of COVID–19 might increase the possibility that CMS will be rewarding ACOs for random variation rather than reductions in spending resulting from ACOs' care management. The commenter indicated there is uncertainty about how the adjustment to performance year expenditures to remove episodes of care for treatment of COVID–19 would affect the ACO when those expenditures are compared against the updated benchmark that reflects a regional and/or national trend.

Response: As discussed in the May 8th COVID–19 IFC, we adjust beneficiary person years to exclude months associated with episodes of care. The ACO's performance year expenditures, adjusted for episodes of care for treatment of COVID–19, will be weighted by person years calculated by Medicare enrollment type (ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid) that are also adjusted to exclude months associated with an episode of care for treatment of COVID–19. To the extent that beneficiaries being hospitalized for treatment of COVID–19 tend to have chronic conditions, the removal of these beneficiaries' months of experience from expenditure calculations could shift more weight to expenditures among healthier beneficiaries. However, as described elsewhere in this section of this final rule, we will also exclude from program calculations beneficiaries' CMS–HCC risk scores from months associated with episodes of care for treatment of COVID–19, which would also cause weighted average risk scores to be similarly weighted towards healthier beneficiaries. We believe that this balanced approach to expenditures and risk scores may mitigate to some degree the commenter's concern about the potential for underrepresentation of beneficiaries' acuity in relation to adjusted expenditures within program calculations leading to windfall savings for ACOs.

Comment: A few commenters pointed to the program's existing policies to limit shared savings, specifically the shared savings rates (under which ACOs may share in a percentage of savings based on quality performance) and the cap on the amount of shared savings that will be paid to an ACO under each track (or payment level within a track), as built in protection against ACOs' receiving windfall shared savings.

Response: We agree with commenters that the sharing rates based on quality performance and the performance payment limits provide some built in protections against windfall shared savings. However, we believe that absent the adjustment for episodes of care for treatment of COVID–19, the Shared Savings Program financial calculations would not fully address the unique expenditure experience resulting from the PHE for COVID–19 and leave ACOs and CMS vulnerable to these variations in Medicare FFS expenditures.

Comment: A few commenters expressed concerns about the mid-year change to the methodology for determining the updated benchmark for performance year 2020 to remove Parts A and B FFS payment amounts for episodes of care for treatment of COVID–19, when the ACO agreed to participate based on the policy that existed prior to the May 8th COVID–19 IFC.

[83] Verma S. 2019 Medicare Shared Savings Program ACO Performance: Lower Costs And Promising Results Under 'Pathways To Success.' *Health Affairs.* September 14, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200914.598838/full/.*

Response: Under § 425.212, an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute: (1) Eligibility requirements concerning the structure and governance of ACOs; and (2) calculation of sharing rate. Typically, we would undertake notice and comment rulemaking to propose modifications to provisions of the program's financial methodology, including to the benchmarking methodology, and subsequently issue a final rule, reflecting any policies that we finalize taking into consideration public comments received on the proposals, prior to the start of any performance year during which such policies would apply. In establishing the adjustment for episodes of care for treatment of COVID–19 in the May 8th COVID–19 IFC, we explained the urgent need for Shared Savings Program ACOs to understand how we would address any distortions in expenditures resulting from the COVID–19 pandemic (85 FR 27579). We found good cause to waive notice and comment procedures for the regulatory changes made to the Shared Savings Program in the May 8th COVID–19 IFC (85 FR 27607 and 27608). In addition, section 1871(e)(1)(A)(ii) of the Act permits the Secretary to issue a rule for the Medicare program with retroactive effect if the failure to do so would be contrary to the public interest. In the May 8th COVID–19 IFC (85 FR 27609), we explained that we believed it would be contrary to the public interest not to implement certain Medicare provisions in the IFC as soon as we were authorized to do so under the authority of section 1871(e)(1)(A)(ii) of the Act, that is retroactively to either the start of the national emergency or the PHE for the COVID–19 pandemic, as applicable. In the case of the adjustment to remove expenditures associated with episodes of care for the treatment of COVID–19, we determined that it would be contrary to the public interest not to implement this adjustment retroactively to the start of the PHE for COVID–19 in January 2020 to ensure that all costs associated with episodes of care for treatment of COVID–19 could be removed from financial calculations for performance year 2020.

Comment: Some commenters expressed uncertainty around whether the full extent of the impact of COVID–19 on ACOs' benchmark and performance year expenditures, and revenue, will be accounted for in the adjustment to program calculations for episodes of care for treatment of COVID–19 triggered by an inpatient service for a patient that has a COVID–19 diagnosis.

Commenters' uncertainty over the adequacy of the adjustment for episodes of care for treatment of COVID–19 often stemmed from the many unknown factors surrounding COVID–19 and the COVID–19 pandemic. For instance, the length and severity of the COVID–19 pandemic and its geographic distribution; the end date of the PHE for COVID–19; long term effects of the virus on patients' health; whether patients may experience worse health outcomes because of postponed or foregone care resulting from widespread delay or cancellation of elective or non-urgent procedures and/or preventive well visits or patients' avoidance of care, and in particular the potential for these circumstances to exacerbate chronic conditions; and the unknown impact of the COVID–19 pandemic on utilization and expenses, including the reduction in elective surgeries that impact revenue, and the potential for increased costs that result from ''catch up'' utilization and expenses for elective services and procedures, as well as the potential for unaccounted for variations in utilization in program calculations.

Some commenters suggested that alternative modifications were necessary in light of their concerns that CMS' approach for adjusting program calculations to remove episodes of care for treatment of COVID–19 triggered by an inpatient service may not be sufficient to address the impact of COVID–19 or the COVID–19 pandemic on ACOs. Commenters offered a variety of alternative approaches, including the following suggestions.

One commenter suggested that CMS disregard ACO financial and quality performance in 2020 to the extent possible, and instead implement an alternative incentive system for ACOs for COVID–19 specific activities, such as by compensating ACOs to focus on COVID–19 surveillance, data collection, and care management activities (particularly for beneficiaries with high risk chronic diseases). This commenter suggested that by disregarding 2020 performance, ACOs and their ACO participants would be allowed to respond to COVID–19 without considering the traditional cost and savings incentives of the Shared Savings Program.

Some commenters suggested modifications to how CMS determines benchmark or performance year expenditures. For example, one commenter suggested the benchmark may need to be increased to offset increased utilization. Another commenter suggested that CMS cap actual performance year 2020 expenditures at an estimate of expected expenditures based on the Shared Savings Program and other benchmark-based population models, similar to the approach used by the Comprehensive Care for Joint Replacement (CJR) model in response to the PHE for COVID–19.

Some commenters suggested that CMS modify the program's payment models for purposes of determining shared savings and shared losses for performance year 2020, such as to: Increase the minimum loss rate corridor to further protect ACOs under two-sided models from shared losses; eliminate shared losses altogether but maintain shared savings; eliminate both shared losses and shared savings; reduce shared losses and reduce shared savings; or eliminate shared losses and reduce shared savings. For example, one commenter suggested that CMS avoid imposition of downside risk for 2020, and cap shared savings at 2 percent of benchmark for ACOs that are eligible to share in savings, and provide bonus payments to ACOs that are not eligible to share in savings but that are still participating in the Shared Savings Program in performance year 2021, such as bonus payment of 0.5 percent of benchmark. These suggestions reflected commenters' differing perspectives. While some commenters believed it was an appropriate trade-off to reduce or eliminate shared savings in combination with reducing or eliminating downside risk, some commenters strongly supported an approach that continued ACOs' ability to fully share in savings generated under the program's existing payment models while protecting ACOs from losses.

Some commenters more generally encouraged CMS to continue to work with ACOs and other program stakeholders, commit to ongoing monitoring or evaluation of the Shared Savings Program, and make adjustments as needed, such as to the participation options, financial methodology, including the benchmarking methodology, beneficiary assignment methodology, and quality measurement methodology.

Response: For the reasons discussed in the May 8th COVID–19 IFC and in this final rule, we believe the adjustment to Shared Savings Program calculations for episodes of care for treatment of COVID–19, which we are finalizing in this final rule, address the impact of COVID–19. We plan to continue to monitor for and consider the impact of the COVID–19 pandemic on ACOs and their ACO participants, and

we would address any additional modifications to Shared Savings Program policies in future notice and comment rulemaking. Therefore, we decline at this time to adopt commenters' suggestions for alternative payment models, alternative approaches to determining benchmark and performance year expenditures, and other modifications to the program's financial calculations. We note that elsewhere in this final rule, we address comments received in response to the May 8th COVID–19 IFC related to changes to the beneficiary assignment methodology (refer to section III.G.5.e of this final rule), and the quality performance requirements for performance year 2020 (refer to section III.I. of this final rule).

Comment: One commenter suggested that CMS consider applying the adjustment for episodes of care for treatment of COVID–19 on a case-by-case basis, for ACOs in areas with higher COVID–19 prevalence, rather than program-wide.

Response: We decline to revise the approach adopted in the May 8th COVID–19 IFC to apply the adjustment for episodes of care for treatment of COVID–19 on a case-by-case basis. Given that ACOs' assigned beneficiary populations are often dispersed across different regions, we believe it would be difficult to fairly and accurately apply the policies on an individual ACO basis when (as commenters point out) the impacts of COVID–19 are variable from region to region. We also believe that a program-wide approach is more reflective of the PHE for COVID–19, which is nationwide. Further, a program-wide approach allows for greater certainty, transparency, and less complexity, than an approach applied on a case-by-case basis when there are more than 500 ACOs actively participating in the program as of January 1, 2020.[84]

Comment: A few commenters expressed their support for an approach that identifies episodes of care triggered by inpatient care for treatment of COVID–19. One commenter stated their belief that CMS struck the right balance of capturing the most variable COVID–19 costs in a well-defined episode.

One commenter explained that the effects of COVID–19 on patients vary greatly, providing as an example that patients who were previously healthy can require lengthy hospitalizations, intubation and mechanical ventilation, and a host of other costly interventions. Consequently, according to this commenter, ACOs and their providers cannot be reasonably expected to manage costs for these patients during an inpatient episode of care. This commenter welcomed the decision by CMS to exclude from Shared Savings Program financial calculations all Parts A and B FFS payment amounts for an episode of care for treatment of COVID–19, triggered by an inpatient service.

Response: We appreciate commenters' support for the approach we adopted in the May 8th COVID–19 IFC, under which an episode of care for treatment of COVID–19 is triggered by an inpatient service.

Comment: A few commenters suggested that there was a lack of clarity around when an episode of care will be triggered by acute care inpatient services for treatment of COVID–19 from facilities not paid under the IPPS, including SNFs. Several commenters asked that CMS clarify that such services will trigger an episode of care when the date of admission occurs within the PHE for COVID–19.

Response: In the May 8th COVID–19 IFC, we adopted an approach to identifying inpatient services for the treatment of COVID–19 provided by non-IPPS providers at § 425.611(b)(1)(ii), which applies when the date of admission occurs within the PHE as defined in § 400.200. Since the issuance of the May 8th COVID–19 IFC, we have determined that this approach to identifying inpatient services for the treatment of COVID–19 provided by non-IPPS providers creates an unintended inconsistency with the approach in § 425.611(b)(1)(i) to identifying inpatient services for the treatment of COVID–19 furnished by IPPS providers eligible for the 20 percent DRG adjustment under section 1886(d)(4)(C) of the Act, which is based on discharges within the PHE for COVID–19. If the approaches are not synchronized, we may (for example) identify fewer inpatient services provided by non-IPPS providers occurring near the start of the PHE for COVID–19, since the admission date for these services would have needed to occur within the PHE, as opposed to the discharge date occurring with the PHE. Further, we may capture more inpatient services furnished by non-IPPS providers at the end of the PHE for COVID–19 because the admission occurs during the PHE, but the discharge does not. This discrepancy could cause a distortion in the effects of the adjustment within program calculations, depending on the type of facility that provides the inpatient service that is the trigger for the episode of care for treatment of COVID–19.

To ensure greater consistency in the description of the policies used to identify inpatient services provided by IPPS and non-IPPS providers that trigger an episode of care for treatment of COVID–19, we are making a revision to the regulation at § 425.611(b)(1)(ii) that establishes the criteria for identifying an episode of care triggered by inpatient services furnished by a non-IPPS provider. We are revising the provision to specify that CMS identifies episodes of care for treatment of COVID–19 based on discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the Public Health Emergency as defined in § 400.200. Furthermore, because the purpose of this revision is to avoid distorting the effects of the adjustment for episodes of care for the treatment of COVID–19 within program calculations, we believe it is in the public interest to use our authority under section 1871(e)(1)(A)(ii) of the Act to apply this change retroactively to the start of the PHE for COVID–19 on January 27, 2020. We note that this is consistent with the applicability date for the original provision, which was also retroactive to the start of the PHE in January 2020, and will help to ensure that adjustments under § 425.611 are made consistently regardless of the type of provider that furnished the inpatient services for COVID–19.

Further, we anticipate identifying inpatient claims that trigger an episode of care for treatment of COVID–19 using all of the following criteria, regardless of whether the claim is submitted by an IPPS or non-IPPS provider. Claims that do not meet these criteria will not trigger an episode of care for treatment of COVID–19.

- Inpatient claims identified by claim type 60.
- Facility type as identified by the character in the third position of the CMS Certification Number (CCN) equal to ''T'' (Rehabilitation Unit) or ''R'' (CAH Rehabilitation Unit), or by the last four digits of the CCN in any of the following ranges: 0001–0879, Short-term (General or Specialty) Hospital; 0880–0899, Hospital that participated in an Office of Research and Development demonstration project; 1300–1399, CAH; 2000–2299, Long-term Care Hospital; 3025–3099, Inpatient Rehabilitation Facility; 3300–3399, Children's Hospital.
- Admission date and discharge date both populated.

[84] CMS, ''Shared Savings Program Fast Facts—As of January 1, 2020'', available at *https://www.cms.gov/files/document/2020-shared-savings-program-fast-facts.pdf.*

• Discharge date between January 27, 2020, and March 31, 2020 (inclusive), and diagnosis code equal to B97.29, or discharge date between April 1, 2020, and expiration date of the PHE for COVID–19 specified in § 400.200 (if known, inclusive) and diagnosis code equal to U07.1. (The applicable diagnosis code may be present in any diagnosis code field based on established coding guidelines.)

We note that the aforementioned criteria were used in identifying episodes of care for treatment of COVID–19 in Q2 and Q3 2020 program reports provided to ACOs. Prior to preparing the Q4 2020 program reports we plan to incorporate an additional criterion that will ensure that expenditures related to treatment of COVID–19 are not excluded from program calculations when the IPPS provider is not eligible to receive the 20 percent DRG adjustment, for example because the provider has specified a billing note NTE02 ''No Pos Test'' on the electronic claim 837I, or a remark ''No Pos Test'' on a paper claim. This note or remark on the claim indicates that the beneficiary did not have a positive laboratory test result for COVID–19 documented in the beneficiary's medical record. This is for consistency with CMS' new requirement that there must be a positive laboratory test result for COVID–19 documented in the beneficiary's medical record in order for an IPPS provider to receive the 20 percent DRG adjustment. This requirement was developed to address potential Medicare program integrity risks, and became effective with admissions occurring on or after September 1, 2020.[85]

Comment: One commenter urged CMS to clarify that an inpatient COVID–19 stay (with proper ICD–10–CM codes and within the PHE for COVID–19) in a SNF, which the commenter indicated was an ''other type of provider'' as described in the May 8th COVID–19 IFC, will be considered a triggering inpatient admission for an episode of care for treatment of COVID–19. This commenter explained that many ACO beneficiaries that reside in long-term care facilities have been transferred from a long-term care bed to a dedicated Medicare-covered bed within the same facility when they were diagnosed with COVID–19, due to the waiver of the 3-day hospital stay in connection with the PHE for COVID–19, as well as hospital capacity issues. These beneficiaries received Part A SNF services in the facility while they remained at that level of care. The commenter further explained that while many of these beneficiaries were never admitted to an acute inpatient hospital for their COVID–19 treatment, they still incurred inpatient COVID–19 related Part A and B costs. This commenter explained that exclusion of these beneficiaries' costs for treatment of COVID–19 from Shared Savings Program calculations is needed to ensure ACOs with long-term care Medicare beneficiaries are not unfairly penalized for treating patients at the inpatient SNF level of care during the pandemic.

Response: Under § 425.611(b)(1)(ii), as modified by this final rule, a discharge for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the IPPS, which would include a SNF, will trigger an episode of care when the date of discharge occurs within the PHE as defined in § 400.200. Elsewhere in this section of this final rule, we have detailed the criteria we will use for identifying claims for inpatient services that trigger an episode of care, which include: Claim type 60, facility type identified based on certain CCNs, admission date and discharge date both populated, and discharge date within the PHE for COVID–19 with a diagnosis code equal to either B97.29 or U07.1 (for an inclusive range of dates). A claim for inpatient services provided in a SNF that meets these criteria would be identified as the trigger for an episode of care for treatment of COVID–19.

We discussed the related issue of services furnished by SNFs under arrangements with an acute care hospital in an FAQ.[86] Under flexibilities adopted in response to the COVID–19 pandemic, a SNF (for example) can work with hospitals under arrangement to be able to provide inpatient acute care to Medicare beneficiaries and these admissions would trigger an excluded COVID–19 episode of care.[87] If a SNF is working under arrangement with a hospital to provide inpatient acute care, we would expect these services to be billed by the hospital which would be one of the CCN types we use to identify an inpatient claim that triggers an episode of care, as described elsewhere in this section of this final rule. However, if the beneficiary's SNF admission is for post-acute services, this alone would not trigger an episode of care for treatment of COVID–19. It is important to note that if post-acute care, such as SNF care, follows a beneficiary's discharge from a facility or unit where they were receiving inpatient services for treatment of COVID–19, payment amounts for post-acute care in the month of and the month following the discharge date (along with all other Parts A and B services) will also be excluded. As specified in § 425.611(b)(2), CMS defines an episode of care for the treatment of COVID–19 as starting in the month in which the inpatient stay begins, as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date.

Comment: When the comment period for the May 8th COVID–19 IFC closed on July 7, 2020, the PHE for COVID–19 extended until July 25, 2020.[88] Some commenters suggested CMS use inpatient services provided after the end of the PHE for COVID–19 to identify episodes of care for treatment of COVID–19. Some commenters suggested that CMS extend the identification of episodes of care for treatment of COVID–19 through the remainder of 2020. One commenter believed this extension was necessary to provide more certainty to ACOs in the event that the PHE is not extended beyond July 25, 2020, expressing concern that there could be a ''second wave'' of infections and a non-continuous PHE scenario. Some commenters suggested that CMS reevaluate whether additional revisions may be necessary to allow the policy to extend into 2021. These commenters explained that these approaches were needed to further protect two-sided model ACOs against financial losses, or more generally to ensure the future success of Shared Savings Program ACOs.

A few commenters suggested CMS remove any end-point to the adjustment. One commenter explained that limiting

[85] For more information, see CMS, MLN Matters, ''New Waivers for Inpatient Prospective Payment Systems (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the Cares Act'' (revised September 11, 2020), available at *https://www.cms.gov/files/document/se20015.pdf.*

[86] CMS, ''COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-For-Service (FFS) Billing'', available at *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.* Refer to section U ''Medicare Shared Savings Program—Accountable Care Organizations (ACO)'' question 29.

[87] Refer to CMS, ''Medicare 1135 Waivers & Two Interim Final Rules Enabling Health System Expansion'', available at *https://www.cms.gov/files/document/covid-19-regulations-waivers-enable-health-system-expansion.pdf.*

[88] Renewal of determination that a public health emergency existed, with an effective date of April 26, 2020, for the duration of the emergency or 90 days, unless extended by the Secretary. Refer to U.S. Department of Health & Human Services, Public Health Emergency web page, ''April 21, 2020: Renewal of the Determination that a Public Health Emergency Exists as the Result of the Continued Consequences of Coronavirus Disease 2019 (COVID–19) (formerly called 2019 Novel Coronavirus (2019–nCoV))'', available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

the adjustment to discharges within the PHE established an artificial cutoff point, which the commenter believed was unnecessary because the adjustment was already limited to a select group of ICD–10–CM diagnosis codes that were inherently tied to the treatment of COVID–19. Another commenter pointed to unknowns about the recovery time of infected individuals, suggesting it may take years to recover. This commenter further indicated that lifting the time limitation on the applicability of the adjustment would help ensure that ACOs are not penalized for having higher COVID–19 spread in their assigned beneficiary populations.

Response: At the time of this final rule, the PHE for COVID–19 has been renewed with an effective date of October 23, 2020, and, unless terminated early, will remain in effect for 90 days after the effective date. Under this extension, we would continue to identify episodes of care for treatment of COVID–19 until at least late-January 2021. Some commenters' suggestions, such as to extend the approach to identifying episodes of care to inpatient services for treatment of COVID–19 for the duration of the performance year 2020, or into 2021, are therefore addressed by the latest renewal of the PHE for COVID–19.

At this time, we decline to adopt the commenters' suggestions to use inpatient services with a discharge date after the end of the PHE for COVID–19 (as defined under § 400.200) to identify an episode of care for treatment of COVID–19 for purposes of adjusting Shared Savings Program calculations. Under the statutory requirements established in section 3710 of the CARES Act, with the conclusion of the PHE, IPPS providers will no longer receive the 20 percent DRG adjustment, which is one factor that the existing adjustment was designed to address.

We recognize that COVID–19 may continue to exist in communities even after the conclusion of the PHE for COVID–19 and that, as a result, some Medicare FFS beneficiaries will likely continue to require higher-cost care, including inpatient care, for the treatment of COVID–19. We believe a number of existing aspects of the Shared Savings Program payment methodology will help to mitigate the impact of these higher costs on ACOs, in the absence of the adjustment for episodes of care for treatment of COVID–19 following the conclusion of the PHE for COVID–19. For instance, as discussed elsewhere in this section of this final rule, the program's existing methodology for updating historical benchmarks, reflecting regional and/or national FFS expenditure trends, will help to ensure that an ACO's benchmark remains comparable with the performance year expenditures, which may include higher costs of care for patients with COVID–19. Further, the program's methodology for truncating assigned beneficiary expenditures, used in calculating benchmark expenditures (§§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4)) and performance year expenditures (§§ 425.604(a)(4), 425.605(a)(3), 425.606(a)(4), 425.610(a)(4)), at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries, will continue to help minimize variation from catastrophically large claims.

We also note that the adjustments for episodes of care for the treatment of COVID–19, as applied for the duration of the PHE for COVID–19, will continue to be reflected in program calculations for the affected time period. In particular, 2020 serves as a performance year for currently participating ACOs, and will be a benchmark year for future program entrants with 2022 and 2023 start dates. In light of the shift to 5-year agreement periods, adjustments made to expenditures during benchmark year 2020 will continue to be reflected in benchmark calculations until the end of performance year 2027 (the final performance year for 2023 starters), under the program's existing policies.

However, we anticipate monitoring the program's calculations for the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. We may revisit the need to extend or modify the adjustment to program calculations in future notice and comment rulemaking.

Comment: One commenter suggested that we exclude short term, CAH swing-bed costs from Shared Savings Program financial calculations during the PHE for COVID–19. This commenter explained that swing-beds in CAHs can be safer for patients in hard-hit COVID–19 areas needing post-acute care than SNFs, but they are paid at approximately 3 times the rate.

Response: CAH swing-bed services, for skilled nursing care, have a ''Z'' in third position of the CCN. Elsewhere in this section of this final rule, we detail the criteria we use for identifying claims for inpatient services that trigger an episode of care for treatment of COVID–19, which include: Claim type 60, facility type identified based on certain CCNs, admission date and discharge date both populated, and discharge date within the PHE for COVID–19 with a diagnosis code equal to either B97.29 or U07.1 (for an inclusive range of dates). According to these criteria, we would not identify a CAH swing-bed service billed by a CCN with ''Z'' in the third position of the CCN, as a trigger for an episode of care for treatment of COVID–19.

However, a claim for inpatient services provided by a CAH may meet the criteria to be identified as the trigger for an episode of care for treatment of COVID–19. For example, if an inpatient service is provided by a CAH, and billed under a CCN identified by ''R'' (CAH Rehabilitation Unit) in the third position of the CCN or with the last four digits of the CCN in the range of 1300–1399 (CAH), this inpatient service would be the basis for an episode of care, if the other previously described criteria are also met. Further, CAH swing-bed services that fall within an episode of care for treatment of COVID–19, triggered by an inpatient admission identified according to the criteria in § 425.611, would also be excluded.

We decline to more broadly exclude all CAH swing-bed costs from the determination of ACO expenditures, which goes beyond the scope of the adjustment for episodes of care for treatment of COVID–19 that we adopted in the May 8th COVID–19 IFC. We believe the existing higher payments for care furnished in swing-beds in CAHs are presently reflected in ACOs' benchmark expenditures. Further adjustments to performance year expenditures to remove all such swing-bed costs would likely exclude expenditures associated with swing bed services that would have been rendered even in the absence of the PHE for COVID–19, creating asymmetry between benchmark and performance year calculations.

Comment: Some commenters suggested that CMS exclude as part of the adjustment for episodes of care for treatment of COVID–19, costs for outpatient services associated with a COVID–19 diagnosis regardless of whether the patient has an inpatient hospital admission. A few commenters explained that the long-term effects of COVID–19 are unknown, and patients may need ongoing care as they recover, and this care may not be provided in the inpatient setting. A few commenters explained that there is an increased cost of care for COVID–19 patients treated solely on an outpatient basis, including increased utilization of high-tech imaging and follow-up care. Pointing to the description in the May 8th COVID–19 IFC in which CMS explained that outpatient care was approximately 10

percent of the cost of hospital care for COVID–19, one commenter noted the costs of outpatient care for beneficiaries who do not have an inpatient admission for treatment of COVID–19 represents potentially sizeable COVID–19-related costs that would not be captured by episodes of care triggered by the receipt of inpatient services for the treatment of COVID–19, particularly for non-hospital-based ACOs.

One commenter, concerned about the impact of increased outpatient care costs of COVID–19 on ACO expenditures, suggested that CMS exclude all COVID–19 related payment amounts from performance year expenditures when these expenses are not reflected in the ACO's benchmark.

Further, a few commenters suggested that CMS monitor the long-term costs of outpatient care for recovered COVID–19 patients, to fully assess the total cost of care implications of the disease. One commenter suggested CMS do so before including these costs in Shared Savings Program benchmark calculations. Another commenter noted it would not expect COVID–19 related outpatient costs to vary significantly within a region, but encouraged CMS to monitor COVID–19 costs outside an episode of care for treatment of COVID–19 as defined in the May 8th COVID–19 IFC.

Response: As one commenter asserted, we would not expect COVID–19 related outpatient costs to vary significantly within a region. Data from quarterly reports appears to support this; as noted elsewhere within this section of this final rule, the distribution of ACO expenditure trends and regional expenditure trends between Q1 and Q2 2020 after removing episodes of care for treatment of COVID–19 are fairly similar. As a result, we believe the program's existing methodology for updating historical benchmarks, which incorporates regional and/or national FFS expenditures trends, should adequately adjust an ACO's benchmark to be more comparable with performance year expenditures by reflecting the changes in outpatient utilization as a result of COVID–19 and the COVID–19 pandemic. For related reasons, we do not believe that changes in outpatient utilization will unfairly impact physician-led ACOs as these changes should also be reflected in the adjusted expenditure trends used to update these ACOs' benchmarks.

We also expect outpatient care for COVID–19 to taper off as a beneficiary's symptoms resolve. As a result, if we were to remove expenditures arising during months of outpatient care for individuals with a diagnosis for COVID–19 that are not already captured by the definition of episode of care for treatment of COVID–19 in § 425.611(b), we could risk removing too many months of care for assigned beneficiaries from program calculations, which in turn could cause benchmarks to become less accurate and disrupt ACOs' shared savings potential.

We decline at this time to modify our approach to exclude all costs for outpatient care for treatment of COVID–19 or, more generally, all costs for treatment of COVID–19. As we have explained elsewhere in this section of this final rule, we believe it is too soon to identify the full extent of the impact of COVID–19 on FFS expenditures. We anticipate monitoring the program's calculations for the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. We may revisit these considerations in future notice and comment rulemaking for the Shared Savings Program.

Comment: A few commenters urged CMS to clarify that an episode of care can be triggered when a COVID–19 diagnosis code is present on a claim and does not need to be the primary diagnosis code to trigger the episode of care. These commenters explained that this will be critical as there has been a large amount of variability in the manner in which COVID–19 diagnoses are listed on claims, due to the often ''multi-system'' nature of COVID–19 related illnesses.

More generally, several commenters cited concerns that inaccuracies in coding of COVID–19 diagnoses, or variations in coding, will affect the accuracy of CMS' adjustment for episodes of care for treatment of COVID–19.

One commenter encouraged CMS to evaluate the accuracy of the episode-based exclusion in capturing true COVID–19 impacts, such as by comparing the episode of care results to regional COVID–19 prevalence.

Response: As we explained in an FAQ,[89] we will identify claims for treatment of COVID–19, for use in identifying episodes of care, when the diagnosis code B97.29 or U07.1 is present in any diagnosis code field. Further, we believe some of the comments reflect a concern that our approach could under-identify episodes of care for the treatment of COVID–19 in the event of inaccuracies in coding. We note that it is incumbent upon providers to accurately code diagnoses and to ensure the accuracy of information submitted on claims based on established coding guidelines. For additional information, refer to guidelines for providers for coding encounters related to COVID–19,[90] and CMS claims processing instructions.[91]

As previously described in this section of this final rule, following the issuance of the May 8th COVID–19 IFC, CMS announced additional requirements for a positive COVID–19 laboratory test documented in the patient's medical record, in order for inpatient services furnished by an IPPS hospital to qualify for the 20 percent DRG adjustment.[92] For purposes of the adjustments to expenditures for episodes of care for the treatment of COVID–19 under the Shared Savings Program, this requirement could further ensure the accuracy of the adjustment for episodes of care for inpatient services identified based on discharges for inpatient services eligible for the 20 percent adjustment, according to § 425.611(b)(1)(i). This requirement would potentially rule out certain episodes of care that would otherwise trigger the adjustment under § 425.611 of the Shared Savings Program regulations.

We appreciate the commenter's suggestion that CMS evaluate the accuracy of the episode-based exclusion in capturing true COVID–19 impacts, and we anticipate continuing to monitor and evaluate the impact of COVID–19 on program calculations, to help inform potential future policy modifications to the Shared Savings Program.

Comment: One commenter expressed concern about how CMS defines an episode of care as ending with the month following the end of the inpatient stay as identified by the discharge date. The commenter explained that an increasing body of evidence suggests that COVID–19 infection may cause a host of lingering

[89] CMS, ''COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-For-Service (FFS) Billing'', available at *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*. Refer to section U ''Medicare Shared Savings Program—Accountable Care Organizations (ACO)'' question 31.

[90] See for example, CDC, ''ICD–10–CM Official Coding and Reporting Guidelines: April 1, 2020 through September 30, 2020'', available at *https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf.*

[91] See for example, CMS, MLN Matters, ''July 2020 Quarterly Update to the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2020 Pricer'', available at *https://www.cms.gov/files/document/mm11764.pdf.*

[92] Refer to CMS, MLN Matters, ''New Waivers for Inpatient Prospective Payment Systems (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the Cares Act'' (revised September 11, 2020), available at *https://www.cms.gov/files/document/se20015.pdf.*

health effects including serious circulatory, respiratory, and neurologic conditions. The commenter also believes additional health issues associated with COVID–19 will likely be identified as more research is done on COVID–19 positive patients. Given the unknowns of this novel virus, the commenter asserts that neither it nor CMS can know that the one-month post discharge end date for a COVID–19 episode will fully address the increased resource demands required to treat these patients. The commenter requested that CMS evaluate and publicly report data on the impacts of COVID–19 on all service utilization for patients with and without an inpatient admission.

Response: We agree with the commenter, regarding the importance of ongoing monitoring of Shared Savings Program calculations for the impact of healthcare utilization resulting from COVID–19 as research helps us better understand the effects of the virus on the Medicare FFS beneficiary population. At this time, we believe that defining an episode of care for the treatment of COVID–19 as set forth in § 425.611(b)(2), as the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date, is sufficient to remove the higher costs of care surrounding an inpatient service for the treatment of COVID–19 with a discharge date within the PHE for COVID–19. Further, to the extent that a beneficiary is subsequently admitted for inpatient care for complications related to COVID–19, following their initial discharge for inpatient services, a claim associated with the new hospitalization would trigger a new episode of care for treatment of COVID–19 if it meets the criteria we described elsewhere in this section of this final rule for identifying inpatient services that trigger an episode of care for treatment of COVID–19, including a discharge date within the PHE for COVID–19.

Comment: One commenter stated its support for the exclusion of affected months associated with an episode of care from total person years used in per capita expenditure calculations.

Response: We appreciate the support for the approach we described in the May 8th COVID–19 IFC (85 FR 27580) of excluding affected months associated with an episode of care from total person years used in per capita expenditure calculations. For consistency within program calculations, we will exclude months associated with episodes of care for the treatment of COVID–19 from program calculations that incorporate monthly data, including the following:

- Calculation of ACO, county, or national level weighted mean CMS-Hierarchical Condition Categories (HCC) prospective risk scores or demographic risk scores used in program risk adjustment calculations described in §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, and 425.610. CMS will exclude monthly prospective beneficiary CMS–HCC risk scores (based on diagnoses from the prior calendar year) from months associated with episodes of care for treatment of COVID–19. CMS will also exclude these months when computing person year values that are used to calculate weighted means of CMS–HCC and/or demographic risk scores across beneficiaries. Note, however, that CMS will continue to use diagnoses that meet risk adjustment criteria from claims submitted by FFS providers for items and services furnished during the months associated with episodes of care for treatment of COVID–19, when calculating final CMS–HCC risk scores for future years. For example, final CMS–HCC risk scores for 2021 will include risk adjustment eligible diagnoses from all eligible claims in 2020, including claims from months associated with episodes of care for treatment of COVID–19. CMS calculates risk scores for all Medicare beneficiaries and these risk scores are used in a variety of calculations across the Medicare Program; CMS does not calculate separate CMS–HCC risk scores for use in Shared Savings Program calculations.

- Calculation of assigned beneficiary person years used in determining the proportion of the ACO's assigned beneficiaries in each county by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) used to weight risk-adjusted county FFS expenditures as described in §§ 425.601(d) and 425.603(f).

- Calculation of the weights applied to national and regional components of the blended growth rates used to trend forward benchmark year (BY) 1 and BY2 expenditures to BY3 according to § 425.601(a)(5) and to update the benchmark according to § 425.601(b).

- Calculation of assigned beneficiary enrollment proportions used to calculate the weighted average across the four Medicare enrollment types in order to obtain a single per capita updated benchmark and a single performance year per capita expenditure value.[93]

- Calculation of total person years used to calculate total benchmark expenditures and total performance year expenditures used in financial reconciliation calculations.[94]

Comment: One commenter asked for clarification of how adjustments to program calculations would be reflected in Shared Savings Program reports provided to ACOs. Specifically, the commenter asked if CMS would provide amended aggregate expenditure/utilization reports for Quarter 1 2020, if payment amounts and beneficiary months associated with episodes of care for treatment of COVID–19 are removed from program calculations going back to January 2020.

Response: In response to the Shared Savings Program policy changes established in the May 8th COVID–19 IFC, CMS added several new report tables to the 2020 quarterly reports, and these modified reports were used to provide Q2 and Q3 2020 data to Shared Savings Program ACOs. Specifically these report changes reflect the adjustment for episodes of care for treatment of COVID–19, and changes to the definition of primary care services used in determining beneficiary assignment as specified in § 425.400(c)(2) and described in section III.G.5.e of this final rule. We anticipate specifying the effects of these policies in quarterly and annual aggregate reports to which they apply. Although we are not reproducing quarterly reports for Q1 2020 to include these updated report variables, we note that the report periods of the Q2, Q3, and Q4 2020 reports include the months of January through March 2020.

Comment: One commenter expressed support for the clarification CMS provided that lump sum payments made to hospitals and other healthcare providers through the CARES Act Provider Relief Fund, that occur outside of Parts A and B claims, will not adversely impact ACO expenditures.

Response: We appreciate the commenter's support for this clarification.

Comment: One commenter suggested that CMS should use the financial

[93] For example, refer to the description of the calculation in Sections 4.1.4 and 4.3.1 of the Shared Savings and Losses and Assignment Methodology Specifications, Version 8, available at *https://www.cms.gov/files/document/shared-savings-losses-assignment-spec-v8.pdf-0.*

[94] For example, refer to the description of the calculation in Section 4.3.1 of the Shared Savings and Losses and Assignment Methodology Specifications, Version 8, available at *https://www.cms.gov/files/document/shared-savings-losses-assignment-spec-v8.pdf-0.*

performance and quality data from 2020 to help stakeholders understand the impact of the global pandemic on ACOs' collective ability to deliver care under the modified coverage and payment policy rules implemented, as well as the impact of the stay-at-home and social distancing recommendations in place throughout the country. The commenter indicated that such data would greatly contribute to future work, including developing higher quality, more cost-efficient models of care after the current pandemic has been contained.

Response: We appreciate the commenter's recommendation that CMS make public data that can assist stakeholders in understanding the impact of COVID–19 and the COVID–19 pandemic on ACOs. CMS makes public certain Shared Savings Program data, such as ACO financial performance data included in annual Shared Savings Program ACO public-use files (PUFs). We anticipate releasing a Shared Savings Program ACO PUF, with ACO-level performance year 2020 financial and quality performance data, in the fall of 2021, following financial reconciliation for performance year 2020. Additional information on program data, including a description of and link to the Shared Savings Program ACO PUF, is available through the Shared Savings Program's ''Program Data'' web page, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-data.* More generally, CMS' ''Medicare COVID–19 Data Snapshot'' resources provide data on COVID–19 cases, and hospitalizations for Medicare beneficiaries diagnosed with COVID–19.[95]

Further, ACOs actively participating in the Shared Savings Program periodically receive data from CMS, which we believe supports their ability to detect and respond to developing trends. Under § 425.702, we provide ACOs with aggregate quarterly reports that identify prospectively and preliminarily prospectively assigned beneficiaries, provide aggregated metrics on the ACO's assigned beneficiary population, and utilization and expenditure data, including expenditure data for the national and regional assignable FFS populations. Under § 425.704, we provide ACOs with monthly claim and claim line feed files with beneficiary-identifiable data, which include Parts A, B, and D data for prospectively and preliminarily prospectively assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant that submits claims for primary care services used in beneficiary assignment. We believe these program reports and data feeds will help ACOs in understanding the impact of COVID–19 on their assigned beneficiaries and the impact of the adjustment for episodes of care for treatment of COVID–19.

Comment: Many commenters commenting on the Shared Savings Program policies adopted in the May 8th COVID–19 IFC suggested it is critical that CMS extend the June 30 deadline for ACOs to voluntarily terminate to avoid financial losses to no earlier than October 31, 2020, with no more than 30-days advance notice of termination, as is currently required under § 425.220(a). The commenters asserted that ACOs need more time and data to make informed decisions about their participation. Commenters explained that absent this protection, ACOs in two-sided models may choose to leave the program given the uncertainty around the end date for the PHE for COVID–19, although the commenters were often unclear in indicating whether their concerns centered around the duration of the adjustment for episodes of care for treatment of COVID–19 or loss mitigation under the program's extreme and uncontrollable circumstances policy (as discussed in section III.G.5.c of this final rule), or both. In further explaining the need for ACOs to have additional time to determine whether to remain in the program, some commenters underscored the uncertainty around a resurgence of the virus in the fall of 2020. In addition, some commenters indicated this flexibility would provide ACOs with more time to focus on the pandemic, which would enable them to remain in the program.

Some commenters suggested that CMS provide two-sided model ACOs the opportunity to voluntarily terminate and avoid financial losses until 90 days following the effective date of the May 8th COVID–19 IFC (which would be approximately August 6, 2020, given the May 8, 2020 effective date of the IFC) to allow these ACOs time to consider the policies established with the IFC. One commenter requested that ACOs in two-sided models be given an opportunity to exit the Shared Savings Program without penalty once the rule is finalized. This commenter (an ACO) explained that the ACO faces a very difficult decision about its continued participation, without enough information, and does not wish to act impulsively.

Response: At this time, we decline to make additional modifications to the Shared Savings Program's policy on payment consequences of early termination. At the time of this final rule, the PHE for COVID–19 has been renewed for a further 90 days, with an effective date of October 23, 2020. Unless the PHE for COVID–19 is terminated early, CMS anticipates mitigating shared losses for the duration of 2020 under the Shared Savings Program's extreme and uncontrollable circumstances policy. We believe this mitigation of shared losses addresses the concerns of ACOs and other program stakeholders regarding the payment consequences of early termination for the remainder of performance year 2020.

Further, we believe we struck an appropriate balance with the combination of policies we established in the May 8th COVID–19 IFC, which provide greater certainty to ACOs and thereby encourage their continued participation in the Shared Savings Program, in particular: Allowing eligible ACOs in the BASIC track's glide path to maintain their current level of participation for performance year 2021 (described in section III.G.5.b of this final rule); adjustments to program calculations for episodes of care for treatment of COVID–19 (described in this section of this final rule); and changes to the Shared Savings Program's assignment methodology (described in section III.G.5.e of this final rule). We believe the stabilizing effect of these policies, along with the application of the program's extreme and uncontrollable circumstances policy for mitigating shared losses beginning in January 2020 and for duration of the PHE for COVID–19 (described in section III.G.5.c of this final rule), is evidenced by the fact that only 4 ACOs (including only 2 ACOs under two-sided models) terminated with an effective termination date on or before June 30, 2020, and therefore, will not be reconciled for performance year 2020. Approximately 35 ACOs, including 12 two-sided model ACOs, have voluntarily terminated their participation, and have requested an end-of-year termination date, and therefore will be reconciled for their performance in the program in performance year 2020.

Comment: Commenters suggested modifications to the Shared Savings Program's benchmarking methodologies, which went beyond the modifications to the program's regulations established in the May 8th COVID–19 IFC.

[95] *CMS.gov,* Preliminary Medicare COVID–19 Data Snapshot, available at *https://www.cms.gov/research-statistics-data-systems/preliminary-medicare-covid-19-data-snapshot.*

Commenters' suggestions included the following:

Some commenters, concerned with anomalies in expenditures and revenue for 2020, suggested alternative approaches to how CMS could treat 2020 data when 2020 is used as a benchmark year in future benchmark calculations.

Some commenters suggested that CMS exclude all 2020 data from future benchmarking calculations, such as excluding 2020 as a benchmark year or excluding 2020 data from the calculation of adjustments to the benchmark. Some commenters suggested alternative approaches to identifying benchmark years, which would avoid reliance on 2020 data. For example, for ACOs entering agreement periods beginning on January 1, 2022, one commenter suggested CMS either use 2017, 2018, and 2019 as the benchmark years (instead of 2019, 2020 and 2021), or combine 2019 and 2021 data.

One commenter suggested that CMS consider changing benchmark year weighting, to limit the impact of 2020 data.

Instead of looking at performance over a single year, one commenter suggested that CMS collaborate with program stakeholders to develop a benchmarking and financial reconciliation methodology for ACOs that spans multiple years.

Some commenters suggested CMS revise the methodology for incorporating factors based on regional FFS expenditures into ACO benchmarks through future rulemaking. Some commenters noted their concern that the blended national and regional expenditure growth rates used to trend and update an ACO's historical benchmark (for agreement periods beginning on July 1, 2019, and in subsequent years) overemphasize the national trend component for ACOs that comprise a large market share in their ACO regional service area, and disadvantage these ACOs. Some commenters expressed concern that including an ACO's assigned beneficiaries in the population used to determine regional FFS expenditures will mean the ACO is compared to itself twice: Once using historical ACO spending and another time by including ACO spending in regional spending. Commenters suggested that CMS revise the program's benchmarking methodology to exclude the ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures, typically in combination with a suggestion that CMS replace the blended national and regional expenditure growth rates with a fully regional trend.

Some commenters were concerned about the risk adjustment approach that applies to ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, and suggested that CMS revise this methodology in future rulemaking. Under the current approach, CMS uses full CMS–HCC risk adjustment for all assigned beneficiaries between the benchmark period (benchmark year 3) and the performance year, subject to a cap of positive 3 percent for the agreement period, and CMS does not apply a cap on negative risk score changes. A few commenters stated that controlling for outliers in risk score increases and decreases is important, explaining this is necessary in the context of the COVID–19 pandemic because of the utilization disruptions and health implications that will affect risk scores. Commenters described the 3 percent cap on risk score increases as ''unreasonably low'' when applied across the agreement period, particularly in light of the higher acuity of beneficiaries resulting from COVID–19 and the other effects of the COVID–19 pandemic such as beneficiaries avoiding preventive services and screenings as well as routine primary care. Commenters explained that the absence of a floor on risk score decreases does not account for artificially low risk scores resulting from circumstances surrounding the COVID–19 pandemic. For example, commenters noted that the two new ICD–10–CM diagnosis codes for COVID–19, ''U07.1 COVID–19, virus identified'' and ''U07.2, COVID–19, virus not identified,'' are not mapped to a Hierarchical Condition Code (HCC), and could therefore cause risk scores to look artificially low. Some commenters suggested that CMS revise the Shared Savings Program's risk adjustment methodology in future rulemaking, such as by increasing the 3 percent cap on risk score growth, such as to 4 percent or 5 percent or eliminating the cap altogether and implementing a floor for risk score decreases, such as between zero (which would prevent any risk score decreases from impacting the benchmark) and negative 5 percent.

Some commenters pointed to concerns that the 3 percent cap on risk score increases under in the risk adjustment methodology for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, is especially problematic for ACOs whose ACO regional service area includes a population of beneficiaries whose risk scores rise more than the cap. One commenter encouraged CMS to adopt a policy of applying a cap on risk score growth after accounting for regional increase in risk scores.

Response: Although the commenters' suggested modifications to the Shared Savings Program's benchmarking methodologies went beyond the scope of the modifications to the program's regulations established in the May 8th COVID–19 IFC, we thank the commenters for their input. We believe it would be premature to specify additional modifications to the program's benchmarking methodology at this time. As we have described elsewhere in this section of this final rule, we believe it is important to continue to monitor the program's calculations and, in particular, the factors used to establish, trend and update the benchmark, to understand the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. As we have also indicated elsewhere in this section of this final rule, it is important to gain additional experience with the benchmarking methodology, established in the Shared Savings Program December 2018 final rule (83 FR 68005 through 68030) and specified in § 425.601, which we believe provides for appropriate incentives for Shared Savings Program ACOs, before making further revisions to the benchmarking methodology. However, we will continue to monitor the impact of the benchmarking methodology and other program policies as part of our efforts to continue to improve and strengthen the program.

Following consideration of the comments received in response to the May 8th COVID–19 IFC on the adjustments to Shared Savings Program calculations to address the COVID–19 pandemic, we are finalizing the regulation at § 425.611, with a modification. As described previously in this section of this final rule, we are revising the regulation at § 425.611(b)(1)(ii) to specify that CMS identifies episodes of care for treatment of COVID–19 based on discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the Public Health Emergency as defined in § 400.200. For the reasons discussed in this section, we are using our authority under section 1871(e)(1)(a)(ii) of the Act to apply this change retroactively to the start of the

PHE for COVID–19. Further, we anticipate monitoring program calculations for the impact of any anomalies in Medicare FFS expenditures resulting from the cost of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. We may revisit, in future notice and comment rulemaking, the need to make other modifications to the program's financial methodology to address the impact of COVID–19 and the COVID–19 pandemic on ACOs.

e. Expansion of Codes Used in Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) and the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018), provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by physicians participating in the ACO and all services furnished by RHCs and Federally Qualified Health Centers (FQHCs) that are ACO participants. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment.

For performance years beginning on January 1, 2019, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(iv) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

- 99201 through 99215 (*codes for office or other outpatient visit for the evaluation and management of a patient*).
- 99304 through 99318 (*codes for professional services furnished in a NF; services identified by these codes furnished in a SNF are excluded*).
- 99319 through 99340 (*codes for patient domiciliary, rest home, or custodial care visit*).
- 99341 through 99350 (*codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12*).
- 99487, 99489 and 99490 (*codes for chronic care management*).
- 99495 and 99496 (*codes for transitional care management services*).
- 99497 and 99498 (*codes for advance care planning*).
- 96160 and 96161 (*codes for administration of health risk assessment*).
- 99354 and 99355 (*add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code*).
- 99484, 99492, 99493 and 99494 (*codes for behavioral health integration services*).

HCPCS codes:

- G0402 (*code for the Welcome to Medicare visit*).
- G0438 and G0439 (*codes for the annual wellness visits*).
- G0463 *(code for services furnished in ETA hospitals).*
- G0506 (*code for chronic care management*).
- G0444 (*code for annual depression screening service*).
- G0442 (*code for alcohol misuse screening service*).
- G0443 (*code for alcohol misuse counseling service*).

On March 17, 2020, we announced the expansion of payment for telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 such that Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence, starting March 6, 2020. In the context of the PHE for COVID–19, we recognize that physicians and other healthcare professionals are faced with new challenges regarding potential exposure risks, including for Medicare beneficiaries, for healthcare providers, and for members of the community at large. For example, the CDC has urged healthcare professionals to make every effort to interview persons under investigation for COVID–19 infection by telephone, text messaging system, or video conference instead of in-person. In the March 31st COVID–19 IFC, to facilitate the use of telecommunications technology as a safe substitute for in-person services, we added, on an interim basis, many services to the list of eligible Medicare telehealth services, eliminated frequency limitations and other requirements associated with particular services furnished via telehealth, and clarified several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks (85 FR 19232).

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe ''face-to-face'' services but are furnished using audio/video, real-time communication technology instead of in-person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID–19 IFC on an interim basis for the duration of the PHE for COVID–19 are already included in the definition of primary care services for purposes of the Shared Savings Program assignment methodology in § 425.400(c)(1)(iv).

The March 31st COVID–19 IFC also established flexibilities for certain services that are furnished virtually using technologies but that are not considered Medicare telehealth services such as virtual check-ins and e-visits as well as telephone E/M services, for which payment has been authorized during the PHE for COVID–19. Prior to the PHE, the codes for these virtual services were not included in the definition of primary care services for purposes of the Shared Savings Program assignment methodology. We explained in the May 8th COVID–19 IFC (85 FR 27582) that we believe it is critical to include these additional codes in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment, so that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for COVID–19 and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth, virtual check-ins, e-visits or telephone, in the definition of primary care services, we ensure that physicians and other practitioners can offer options to beneficiaries whom they treat, while also allowing this care to be included in our consideration of where beneficiaries receive the plurality of their primary care for purposes of assigning

beneficiaries to ACOs. As a result, revising the definition of primary care services used in assignment to include these services further allows for continuity and coordination of care. We also reiterated our policy defined at § 425.404(b) that, for performance years starting on January 1, 2019, and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

(2) Use of Codes for Virtual Check-Ins, Remote Evaluation E-Visits, Telephone Evaluation and Management Services, and Telehealth in Beneficiary Assignment

As we described in the May 8th COVID–19 IFC (85 FR 27583 through 27586), based on feedback from ACOs and the expansion of payment, on an interim basis, for the virtual services discussed above, we revised the definition of primary care services used in the Shared Savings Program assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19, as defined in § 400.200, to include the following additions: (1) HCPCS code G2010 (*remote evaluation of patient video/images*) and HCPCS code G2012 (*virtual check-in*); (2) CPT codes 99421, 99422 and 99423 (*online digital evaluation and management service (e-visit)*); and (3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*).

We explained that because the services are similar to and may replace an E/M service for a beneficiary, we believed it would be appropriate to include these CPT and HCPCS codes in the definition of primary care services used for assignment because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We explained our belief that it is important to include these services in our assignment methodology because we determine assignment to ACOs based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. Including these codes in the definition of primary care services used in assignment for performance years during the PHE for COVID–19 results in a more accurate identification of where beneficiaries have received the plurality of their primary care services.

In the May 8th COVID–19 IFC (85 FR 27583), we also clarified that CPT codes 99304, 99305 and 99306, 99315 and 99316, 99327 and 99328, 99334 through 99337, 99341 through 99345, and 99347 through 99350 will be included in the assignment methodology when these services are furnished using telehealth, consistent with additions to the Medicare telehealth list for the duration of the PHE for COVID–19 as discussed in the March 31st COVID–19 IFC (85 FR 19235 through 19237). We use the assignment methodology described in §§ 425.402 and 425.404 for purposes of assigning beneficiaries to ACOs for a performance year or benchmark year based on preliminary prospective assignment with retrospective reconciliation (including quarterly updates) or prospective assignment.

We explained that with the emergence of the virus that causes COVID–19, there is an urgency to expand the use of technology to allow people who need routine care, vulnerable beneficiaries, and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. Limiting community spread of the virus, as well as limiting beneficiaries' exposure to other patients and healthcare staff members, will slow viral spread. We explained that we anticipated that the patterns and types of care provided during the PHE for COVID–19 would be different, and that it was important to capture these changes in the methodology used to assign beneficiaries to ACOs as soon as possible. We explained this was particularly important for ACOs under preliminary prospective assignment with retrospective reconciliation for PY 2020, so that they can understand the beneficiary population for which they will be responsible during PY 2020.

As discussed in the March 31st COVID–19 IFC (85 FR 19244), in the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not Medicare telehealth services. Specifically, beginning with CY 2019, we finalized separate payment for remote evaluation of video and/or images, HCPCS code G2010 *(Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment),* and virtual check-in, HCPCS code G2012 *(Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion).*

These codes were finalized as part of the set of codes that is only reportable by the physicians and practitioners who can furnish E/M services. Per the March 31st COVID–19 IFC, on an interim basis for the PHE for COVID–19, we allow these codes to be used for new patients. In the March 31st COVID–19 IFC (85 FR 19244), we explained that, in the context of the PHE for COVID–19, when brief communications with practitioners and other non-face-to-face services might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we believe that these services should be available to as large a population of Medicare beneficiaries as possible. In some cases, use of telecommunication technology could mitigate the exposure risk, and in such cases, the clinical benefit of using technology to furnish the service is self-apparent. This would be especially true should a significant increase in the number of people or healthcare professionals needing treatment or isolation occur in a way that would limit access to brief communications with established providers. Therefore, on an interim basis, during the PHE for COVID–19, we finalized that these services, which may only be reported if they do not result in a visit, including a telehealth visit, can be furnished to both new and established patients

As discussed in the March 31st COVID–19 IFC (85 FR 19254), in the CY 2019 PFS final rule (83 FR 59452), we finalized payment for new online digital assessment services, also referred to as ''E-Visits,'' beginning with CY 2020 for practitioners billing under the PFS. These are non-face-to-face, patient-initiated communications using online patient portals. These digital assessment services are for established patients who require a clinical decision that otherwise typically would have been provided in the office. Per the March 31st COVID–19 IFC (85 FR 19244), while the code descriptors for these e-visit codes refer to an ''established patient'', during the PHE for COVID–19, we are exercising enforcement

discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Practitioners who may independently bill Medicare for E/M visits (for instance, physicians and NPs) can bill the following codes:

• 99421 *(Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.)*

• 99422 *(Online digital evaluation and management service, for an established patient, for up to 7 days cumulative time during the 7 days; 11–20 minutes.)*

• 99423 *(Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.)*

In the May 8th COVID–19 IFC (85 FR 27584), we explained that we also considered adding additional e-visit HCPCS codes that are used by clinicians who may not independently bill for E/M visits and who are not included in the definition of ACO professional in § 425.20 (for example, PTs, OTs, SLPs, CPs). However, because these services are not furnished by ACO professionals, we determined it was not necessary to include the following codes in our definition of primary care services for use in assignment:

• G2061 *(Qualified non-physician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes.)*

• G2062 *(Qualified non-physician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes.)*

• G2063 *(Qualified non-physician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes.)*

As discussed in the March 31st COVID–19 IFC (85 FR 19264 through 19265) and in the May 8th COVID–19 IFC, CMS finalized, on an interim basis for the duration of the PHE for COVID–19, separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. While the code descriptors for these services refer to an ''established patient'', CMS has indicated in the COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing (*https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*) that during the PHE for COVID–19 we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Practitioners who may independently bill Medicare for E/M visits (for instance, physicians and NPs) can bill the following codes:

• 99441 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.)*

• 99442 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion.)*

• 99443 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion.)*

In the May 8th COVID–19 IFC (85 FR 27584), we explained that we also considered adding the additional telephone assessment and management CPT codes that are used by clinicians who may not independently bill for E/M visits and who are not included in the definition of ACO professional in § 425.20 (for example, PTs, OTs, SLPs, CPs). However, because these services are not furnished by ACO professionals, we determined it was not necessary to include these codes in our definition of primary care services for use in assignment:

• 98966 *(Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.)*

• 98967 *(Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion.)*

• 98968 *(Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion.)*

We also explained that several codes, detailed below, that are included on the ''Covered Telehealth Services for PHE for the COVID–19 pandemic, effective March 1, 2020'' list available at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*, are already included in the definition of primary care services used in the Shared Savings Program assignment methodology:

• 99304 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)*

• 99305 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or*

family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)

• 99306 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.)*

• 99315 *(Nursing facility discharge day management; 30 minutes or less.)*

• 99316 *(Nursing facility discharge day management; more than 30 minutes.)*

• 99327 *(Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.)*

• 99328 *(Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.)*

• 99334 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.)*

• 99335 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.)*

• 99336 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.)*

• 99337 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.)*

• 99341 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.)*

• 99342 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.)*

• 99343 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.)*

• 99344 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.)*

• 99345 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high*

complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.)

- 99347 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.)*
- 99348 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.)*
- 99349 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.)*
- 99350 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.)*

We clarified that because these CPT codes are already included in the definition of primary care services used in the Shared Savings Program assignment methodology, these CPT codes would continue to be included in the definition of primary care services used for assignment, including when they are furnished via telehealth during the PHE for COVID–19, beginning March 1, 2020. We explained our belief that it is important to include these services in our assignment methodology, regardless of whether they are furnished in-person or via telehealth, because we determine assignment based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. We explained that including these codes in the definition of primary care services used in assignment during the PHE for COVID–19, even when services are furnished via telehealth, would result in a more accurate identification of where beneficiaries receive the plurality of their primary care services.

Accordingly, we added paragraph (c)(2) to our regulation at § 425.400, in which we specified additional primary care service codes that would be considered for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19, as defined in § 400.200. Under this provision the existing CPT codes and HCPCS codes included in the definition of primary care services at § 425.400(c)(1) continue to apply for purposes of determining beneficiary assignment under § 425.402.

We received public comments on the revisions to the definition of primary care services for purposes of assignment that we adopted in the May 8th COVID–19 IFC, including the alternative considered with regard to adding codes used by non-ACO professionals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the addition of the telemedicine, e-visits, and virtual services to the list of primary care services used for purposes of beneficiary assignment during the PHE for COVID–19. Commenters noted that the expansion of the definition of primary care services will allow ACOs to continue managing their patient populations but also advised CMS to monitor closely for unintended consequences. Commenters also noted that the expanded definition will allow CMS to accurately identify where beneficiaries receive the plurality of their primary care services during the PHE, which is critical for the stability of ACOs and primary care physicians transitioning into value-based payment arrangements. The revised definition also protects ACOs from undue declines in their assigned beneficiary populations due to the transition to telehealth services. Other commenters supported the expanded definition of primary care services used for assignment, as telehealth has proven to be critical for many independent physicians and practices during the pandemic. More patients than ever are using telehealth as a routine part of their care, and more clinicians and hospitals are offering it. Incorporating these services into the assignment methodology ensures that ACOs are rewarded for their efforts to transform their practices from in-person to virtual to support social distancing, as necessary during the PHE for COVID–19. Another commenter supported this change and appreciated the Agency's recognition of the increased delivery of care through telehealth due to the pandemic and the clarification that services included in the existing definition of primary care services would be considered in assignment when furnished in accordance with the telehealth rules.

However, commenters cautioned against unintended consequences. One such unintended consequence could be assignment to ACOs of beneficiaries residing in states from which the ACO had not previously received assigned beneficiaries. One commenter encouraged CMS to develop clear guardrails for patient attribution that balance the expanded role of telehealth post-COVID–19 with the potential for healthcare providers to reach patients far outside their normal geographic region. Another commenter believed this expansion may result in a patient

being attributed to the ACO through a telehealth visit with an ACO professional, and that ACO subsequently becoming responsible for the cost and quality of care of that patient, who may not continue to see ACO professionals participating in that ACO once the pandemic ends. A few commenters expressed their belief that the expansion of virtual services provided during the PHE for COVID–19 will result in telemedicine continuing to be a significant mode of providing clinical services as the COVID–19 pandemic continues, and in the post-COVID–19 era.

Response: We appreciate the comment that the expansion of the definition of primary care services for the duration of the PHE for COVID–19 will allow ACOs to effectively manage their patient populations. We believe that the revised definition will allow ACOs and their ACO participants to make determinations regarding the appropriate and effective use of telehealth and in-person services based on the needs of the beneficiary balanced with safety considerations during the PHE for COVID–19. By expanding the definition, ACOs will not be penalized if they elect to furnish more services through telehealth and telemedicine during the PHE for COVID–19.

We have continued to monitor assignment data for anomalies. In the first quarter of 2020, we observed a significant drop in the utilization of HCPCS and CPT codes used in assignment; however, as of the third quarter of 2020, utilization of these codes, including the new codes added in the May 8th COVID–19 IFC, has rebounded to near typical utilization.

Further, as of the third quarter of 2020, we are seeing minimal decreases in assigned and assignable beneficiaries for ACOs participating under preliminary prospective assignment, similar to percentage decreases seen when comparing assignable and assigned beneficiaries in Q1 to assignable and assigned beneficiaries in Q3 of 2019. For 2019, the Q1 to Q3 average decrease in assigned beneficiaries was less than 1 percent. For 2020, the Q1 to Q3 average decrease in assigned beneficiaries is 3 percent. The average decrease in assignable beneficiaries from Q1 to Q3 of 2019 was less than one percent while the average decrease in assignable beneficiaries from Q1 to Q3 of 2020 is less than 5 percent. These minor average differences indicate that the PHE for COVID–19 is not having a large impact on beneficiary assignment for ACOs under preliminary prospective assignment.

We also continue to monitor rates of beneficiary churn, that is, the rate at which beneficiaries are assigned to an ACO and subsequently not assigned to that ACO; through the third quarter of 2020, rates of beneficiary churn remain consistent with rates seen prior to the PHE for COVID–19. The consistent rates of beneficiary churn indicate that the majority of beneficiaries continue to receive the plurality of their services from healthcare providers who participate in the ACO to which they were assigned at the start of the performance year. Our analyses also indicate that, on average, ACOs are losing fewer beneficiaries to competition with other ACOs and non-ACO affiliated healthcare providers during 2020 than were lost during 2019. Based on these findings, we believe that the PHE for COVID–19 is not having a significant impact on beneficiary retention.

With regard to comments that ACOs may have beneficiaries assigned to them based on telehealth visits, including beneficiaries that reside outside the ACO's normal geographic region, and those beneficiaries may not receive in-person services from ACO professionals after the PHE for COVID–19 ends, we do not believe that this is a concern for the Shared Savings Program because we continue to determine assignment based upon where beneficiaries receive the plurality of their primary care services and whether beneficiaries have designated an ACO professional as their primary clinician. Our analysis through the third quarter of 2020 indicates that the utilization of telehealth and telemedicine services is beginning to decrease, and in-person visits are beginning to rebound. To the extent that beneficiaries who had been receiving telehealth and telemedicine services from an ACO professional return to receiving in-person services from other healthcare providers (outside the ACO), assignment based on the plurality of primary care services will result in beneficiaries being assigned appropriately.

Finally, we agree with commenters that telemedicine will likely continue to be a significant mode of providing clinical services and we will continue to refine the definition of primary care services, as appropriate, in future rulemaking.

Comment: Several commenters requested that CMS clarify that the agency's existing policy has been to consider all codes listed in § 425.400(c)(1)(iv) when performing beneficiary assignment even when those services that are eligible for telehealth are delivered via telehealth. They suggested that such a clarification would mitigate confusion and emphasize the importance of these services in assignment.

Response: We appreciate this request for clarification. CMS maintains a list of services that are payable under the Medicare Physician Fee Schedule when furnished via telehealth (*https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*). Several of the codes included on the List of Telehealth Services are also included in the Shared Savings Program definition of primary care services for purposes of assigning beneficiaries. Specifically, we clarify that those HCPCS and CPT codes included in the List of Telehealth Services that are also included in the Shared Savings Program definition of primary care services for purposes of assignment are used for assignment regardless of whether they are furnished in person or via telehealth, provided they are billable and payable under Medicare FFS payment policies and a specific place of service exclusion is not included for the codes in our assignment methodology.

Comment: One commenter expressed concern about the special assignment rules for services furnished in Electing Teaching Amendment (ETA) hospitals. Specifically, the commenter was concerned that only institutional claims (Part A claims) for services furnished in these hospitals are used in assignment calculations. The commenter expressed concern that beneficiaries who would have been assigned to an ACO in which an ETA hospital is participating based on in-person office visits at the ETA hospital will not be assigned to the ACO on the basis of telemedicine services, even if these services were provided by one of the physicians within its network, by which we assume the commenter means physicians that practice in the ETA hospital and bill through the ETA hospital's TIN that is included on the ACO's ACO participant list. This commenter urged CMS to examine the impact of this issue and to update the beneficiary assignment methodology immediately. This commenter also urged CMS to continue attributing Medicare beneficiaries to ACOs with Electing Teaching Hospitals (ETAs) as ACO participants through Institutional/Part A claims, but to include telehealth encounters billed under Institutional/Part A claims (that is, claims under HCPCS code Q3014).

Response: We appreciate the commenter's concern regarding the special assignment rules for ETA hospitals that rely on institutional claims. However, because we did not

include institutional claims billed under HCPCS code Q3014 as part of the revisions to the definition of ''primary care services'' in the May 8th COVID–19 IFC, or otherwise propose to add this code to the definition of primary care services used for assignment, we cannot finalize its inclusion as part of this final rule. We also note section 1899(c) of the Act, which governs the assignment process under the Shared Savings Program, and the implementing regulations at part 425 subpart E, make clear that assignment is based upon primary care services furnished by certain practitioners, and services reported on claims from FQHCs and RHCs, which are treated as primary care services performed by a primary care physician. Because HCPCS code Q3014 describes a telehealth originating facility site fee that is billable by the site hosting the patient rather than the distant site physician or practitioner who is furnishing the service and does not identify the actual service that was furnished during the telehealth visit, it does not represent a primary care service that may be considered in the assignment methodology under the Shared Savings Program.

Comment: Some commenters expressed concerns about anomalous CY 2020 utilization patterns impacting beneficiary assignment. For example, as one commenter detailed, the COVID–19 pandemic could cause an overall decrease in assigned beneficiaries, and change the demographics of the assigned population (including beneficiaries' CMS–HCC risk profiles). Some commenters were especially concerned about the impact on ACOs under prospective assignment. For example, one commenter explained that these ACOs may experience a disproportionate increase in their average risk score, due to the loss of relatively healthy beneficiaries who were assigned to an ACO based on only 1–2 visits as beneficiaries' care-seeking behaviors have changed as a result of the pandemic (for example, receiving care through telehealth outside the ACO, sheltering in a different geographic location and receiving services from healthcare providers there, and deferring or foregoing routine care). Some commenters suggested that CMS address the impact of atypical patterns of care on beneficiary assignment by adjusting the data used in determining assignment. For instance, a few commenters suggested that CMS disregard 2020 data when determining assignment for benchmark or performance years, but did not provide detailed suggestions for an alternative approach. Some commenters suggested that CMS use an extended assignment window for determining PY 2021 prospective assignment, such as a 24-month or 18-month assignment window instead of a 12-month assignment window, which would include months during 2020. One commenter suggested that CMS carefully review the methodology to ensure that beneficiary assignment is fair and equitable.

Response: We continue to monitor assignment trends. To date, we have seen minimal decreases in the overall number of beneficiaries assigned to ACOs participating in the Shared Savings Program, with a slight decrease (−3.0 percent) in the median number of beneficiaries assigned to individual ACOs between Q1 and Q3 2020. We interpret the comments suggesting that we disregard 2020 data in benchmark and performance year assignment to mean that CMS should not use fee-for-service claims with dates of service in 2020 to assign beneficiaries, and instead determine alternate assignment windows that do not include 2020. At this time, we are not adopting commenters' suggestions to disregard 2020 data in benchmark year and performance year assignment, or to redefine the assignment window for PY 2021 prospective assignment to include additional months, as our analyses of assignment and utilization trends indicate such policy updates are not necessary. We will continue to monitor the impact of the PHE for COVID–19 on assignment and may consider proposing changes in future notice and comment rulemaking if warranted.

(3) Applicability of Expanded Definition of Primary Care Services

After further consideration of our existing beneficiary assignment methodology in part 425, subpart E, which includes the use of an assignment window to conduct beneficiary assignment for both benchmark and performance years, we have determined that it is necessary to modify § 425.400(c)(2) to better reflect the way in which we conduct assignment for the Shared Savings Program.

In the June 2015 final rule (80 FR 32699) we finalized the definition of ''assignment window'' under § 425.20 to mean the 12-month period used to assign beneficiaries to an ACO. As described in the December 2018 final rule, the assignment window for ACOs under prospective assignment is a 12-month period off-set from the calendar year, while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year (83 FR 67861). Operationally, in determining beneficiary assignment for each performance year and benchmark year, we identify allowed charges for services billed under the HCPCS and CPT codes included in the applicable definition of primary care services under § 425.400(c), and according to the methodology specified in subpart E of the Shared Savings Program's regulations, during all months of the 12-month period of the assignment window.

The new provision at § 425.400(c)(2) states that we will apply the expanded definition of primary care services, which includes codes for virtual check-ins, remote evaluation e-visits, telephone E/M services, and telehealth, to determine beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19 as defined in § 400.200. We have determined it is necessary to modify the provision to make clear that the expanded definition of primary care services will apply not only to assignment for performance years during the PHE for COVID–19, but also to assignment for any benchmark years during the PHE.

To further clarify the applicability of the expanded definition of primary care services, we believe it is necessary to specify when a performance year's or benchmark year's assignment is affected by the PHE for COVID–19, because the assignment window for such years may span a period which includes months during or outside the PHE for COVID–19. For consistency with our operational approach, we believe it is necessary to apply the definition of primary care services consistently to all months of the assignment window. Further, because the HCPCS and CPT codes included in the expanded definition of primary care services in § 425.400(c)(2) capture the unique utilization patterns during the PHE for COVID–19, we believe that applying this expanded definition to all months of the assignment window will help ensure we are appropriately identifying the ACO's assigned population that will be used in determining ACOs' financial performance.

As discussed in section III.G.2.a of this final rule, we are finalizing the inclusion of online digital E/M services CPT codes (99421, 99422, and 99423) and HCPCS codes G2010 (code for the remote evaluation of patient video/images) and G2012 (code for virtual check-in) in the definition of primary care services under § 425.400(c)(1)(v), applicable for the performance year

starting on January 1, 2021, and subsequent performance years. The telephone E/M services CPT codes (99441, 99442, and 99443), included in the expanded definition of assignment under § 425.400(c)(2) but not under § 425.400(c)(1), are not payable under the Medicare Physician Fee Schedule payment rules outside of the PHE for COVID–19. We anticipate that applying the telephone E/M services CPT codes to months of the assignment window that occur outside of the PHE for COVID–19 will have a limited impact on assignment.

Therefore, we are revising § 425.400(c)(2) to make clear that we will use the expanded definition of primary care services to identify allowed charges used in beneficiary assignment when the assignment window for a benchmark or performance year includes any month(s) during the PHE for COVID–19, as defined in § 400.200. Furthermore, in determining beneficiary assignment, we will consider services billed under the additional primary care service codes specified in § 425.400(c)(2) during all months of the assignment window, including months that occur outside of the PHE for COVID–19.

The following example illustrates the applicability of the approach we are finalizing. For ACOs under prospective assignment, beneficiary assignment for PY 2021 will be based on the October 1, 2019, through September 30, 2020 assignment window, which includes months before the start of and during the PHE for COVID–19. Accordingly, we will consider any services billed under the additional primary care service codes specified in § 425.400(c)(2) during this assignment window when conducting beneficiary assignment for PY 2021. Further, we will use this same approach in determining prospective assignment for 2021 when it serves as a benchmark year.

We also wish to clarify that the expanded definition of primary care services specified in § 425.400(c)(2) does not apply for purposes of determining prospective assignment for PY 2020, or under prospective assignment for 2020 when it serves as a benchmark year, because the months in the assignment window were not during the PHE for COVID–19. Prospective assignment is completed before the start of the performance year, according to § 425.400(a)(3). Although we may make certain adjustments to remove beneficiaries from an ACO's prospective assignment list if they are no longer eligible for assignment according to § 425.401(b), we do not add beneficiaries to an ACO's prospective assignment list after the start of the performance year, as described in earlier rulemaking (see for example, 80 FR 32774 and 32775). Prospective assignment for PY 2020 was completed prior to the start of the PHE for COVID–19, based on services furnished during the assignment window from October 1, 2018, through September 30, 2019. As a result, we do not believe it is either necessary to address the change in care patterns during the PHE for COVID–19 or consistent with the prospective assignment methodology in § 425.400(a)(3) to update PY 2020 beneficiary assignment for ACOs under prospective assignment to reflect utilization of the primary care services specified in § 425.400(c)(2) during the assignment window for the performance year.

Accordingly, for clarity and greater consistency with the beneficiary assignment methodology in part 425, subpart E, we are revising the text of the regulation at § 425.400(c)(2) to specify that the additional primary care service codes will be used in conducting beneficiary assignment when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the PHE for COVID–19 defined in § 400.200. We are also adding a new provision at § 425.400(c)(2)(ii) to specify that we will apply the additional primary care service codes, specified in § 425.400(c)(2)(i) (as renumbered), to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) of the PHE for COVID–19 as defined in § 400.200. We are also making conforming revisions to renumber the existing provisions of the regulation at § 425.400(c)(2) to reflect this addition.

In the May 8th COVID–19 IFC (85 FR 27583), we determined that there was good cause to waive prior notice and comment rulemaking in order to implement the expanded definition of primary care services in § 425.400(c) immediately for purposes of determining beneficiary assignment for PY 2020. In addition, we also explained that we believed it would be contrary to the public interest not to implement certain Medicare provisions in the IFC as soon as we were authorized to do so under the authority of section 1871(e)(1)(A)(ii) of the Act, that is, retroactively to either the start of the national emergency or the PHE for the COVID–19 pandemic, as applicable (85 FR 27609). Because the revisions we are making to § 425.400(c)(2) in this final rule are intended to clarify the applicability of the expanded definition of primary care services to the determination of beneficiary assignment, we believe it is in the public interest to use our authority under section 1871(e)(1)(A)(ii) of the Act to apply this change retroactively to ensure that it applies to the determination of beneficiary assignment under § 425.400(a)(2) for the performance year starting on January 1, 2020, for ACOs under preliminary prospective assignment with retrospective reconciliation. We note that this is consistent with the applicability date for the provision as originally adopted in the May 8th COVID–19 IFC (see 85 FR 27551, 27609).

We will apply this expanded definition of primary care services, as revised, to determine beneficiary assignment for ACOs under prospective assignment according to § 425.400(a)(3), and for ACOs under preliminary prospective assignment with retrospective reconciliation according to § 425.400(a)(2). The revised definition is also applicable for purposes of determining beneficiary assignment for Track 1+ Model ACOs in the same way in which it applies to Shared Savings Program ACOs under prospective assignment according to § 425.400(a)(3).[96] We also note that we will apply this revised definition consistently when performing beneficiary assignment in program operations, which includes (for example), determining the ACO's performance year assigned population, determining the assigned population for purposes of producing quarterly assignment list reports and quarterly aggregate reports for ACOs, and determining assignment for benchmark years.

In summary, following consideration of the comments received in response to the May 8th COVID–19 IFC, we are finalizing the regulation at § 425.400(c)(2) with modifications. We are finalizing the use of the following additional primary care codes in determining beneficiary assignment when the assignment window (as defined at § 425.20) for a benchmark or performance year includes any months during the PHE for COVID–19 defined in § 400.200: (1) HCPCS code G2010 (*remote evaluation of patient video/images*) and HCPCS code G2012 (*virtual check-in*); (2) CPT codes 99421, 99422 and 99423 (*online digital evaluation and management service (e-visit)*); and

[96] Refer to the terms of the Track 1+ Model Participation Agreement, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

(3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*). Additionally, in this final rule we are revising the regulation to add a new provision at § 425.400(c)(2)(ii) to specify that we will apply the additional primary care service codes, specified in § 425.400(c)(2)(i) (as renumbered), to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) during the PHE for COVID–19 defined in § 400.200.

f. Applicability of Policies to Track 1+ Model ACOs

In the May 8th COVID–19 IFC (85 FR 27586 and 27587), we provided a comprehensive discussion of the applicability of policies, either clarified or modified by the IFC, to Track 1+ Model ACOs. We explained which changes to Shared Savings Program regulations would apply to Track 1+ Model ACOs, and which changes in policies would become applicable to Track 1+ Model ACOs through an amendment to the ACO's Track 1+ Model Participation Agreement.[97]

Generally, comments regarding the application of policies discussed in the May 8th COVID–19 IFC, to Track 1+ Model ACOs have been addressed as part of the discussion of those policies elsewhere in section III.G.5 of this final rule. Accordingly, rather than repeating comments related to the applicability of these policies to ACOs participating in the Track 1+ Model, we refer readers to the relevant discussion in section III.G.5. of this final rule.

H. Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy Services

Section 5012 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255; enacted December 13, 2016) created a separate Medicare Part B benefit under section 1861(s)(2)(GG) and section 1861(iii) of the Act to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment, effective for January 1, 2021. Section 5012 of the Cures Act also added section 1834(u) to the Act, which establishes the payment and related requirements for home infusion therapy under this benefit. Section 1834(u)(6) of the Act requires that, prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan of care described in section 1861(iii)(1) of the Act shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, HOPD) for the furnishing of infusion therapy under this part.

As discussed in the 2021 PFS proposed rule, (85 FR 50074), we recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy treatment options. We solicited comments in the CY 2020 PFS proposed rule (84 FR 40716) and the CY 2020 HH PPS proposed rule (84 FR 34694), regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also invited comments on any additional interpretations of this notification requirement. We summarized the comments received in the CY 2020 PFS final rule (84 FR 62568) and the CY 2020 HH PPS final rule (84 FR 60478), and we stated we would take these comments into consideration as we continue developing future policy through notice-and-comment rulemaking.

Many commenters stated that physicians already routinely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. For home infusion therapy services effective beginning CY 2021, physicians are to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. We did not propose to create a mandatory form nor did we propose to require a specific manner or frequency of notification of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, as we believe that current practice provides appropriate notification. However, we noted that if current practice is later found to be insufficient in providing appropriate notification to patients of the available infusion options under Part B, we may consider additional requirements regarding this notification in future rulemaking. We referred stakeholders to the CY 2020 HH PPS final rule (84 FR 60478) for further information regarding the policies on home infusion therapy services beginning CY 2021 and for subsequent years.

In response to the 2021 PFS proposed rule, (85 FR 50252), we received 14 public comments, all in support of physicians continuing with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. Two of these commenters mentioned other issues that were discussed in the CY 2020 HH PPS final rule (84 FR 60478) regarding the general home infusion therapy services policy. After consideration of these comments, and since we did not propose any specific requirements, we are not adopting specific notification requirements in this final rule. Rather, as noted previously, if current practice is later found to be insufficient, we may consider additional requirements regarding this notification in future rulemaking. Stakeholders may refer to the CY 2020 HH PPS final rule (84 FR 60478) for further information regarding the policies on home infusion therapy services beginning CY 2021.

I. Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

Following the hurricanes and wildfires during 2017, we issued an IFC, entitled ''Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017,'' which appeared in the December 26, 2017 **Federal Register** (82 FR 60912) (hereinafter referred to as the ''December 2017 IFC''). The December 2017 IFC established a policy for determining quality performance scores for ACOs, when the ACO was impacted by extreme and uncontrollable circumstances such as hurricanes, wildfires, or other triggering events, in performance year 2017, including the applicable quality reporting period for the performance year if the quality reporting period was not extended. In the CY 2019 PFS final rule, we extended the policies finalized in 2017 to performance year 2018 and subsequent performance years. In the March 31st COVID–19 IFC (85 FR 19267 and 19268), we updated the extreme and uncontrollable circumstances policy to eliminate the restriction that the policy applies only if the quality reporting period is not extended.

We determine whether an ACO has been impacted by an extreme and

[97] See for example, the Medicare ACO Track 1+ Model Participation Agreement, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

uncontrollable circumstance using the following criteria:

- 20 percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance (§ 425.502(f)(1)(i)).
- The ACO's legal entity is physically located in an area identified as being affected by an extreme and uncontrollable circumstance under the Quality Payment Program (§ 425.502(f)(1)(ii)).

Under the current regulation at § 425.502(f)(2), ACOs that meet one or both of the above criteria will have their quality performance score set to equal the mean quality performance score for all Shared Savings Program ACOs for the relevant performance year. However, if an ACO that meets one or both of the criteria above completely and accurately reports all quality measures, we use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs to calculate the ACO's quality performance score.

The PHE for COVID–19 applies to all counties in the United States, and therefore, for performance year 2020 all ACOs are considered to be affected by an extreme and uncontrollable circumstance.

1. Changes to the CAHPS for ACOs Reporting Requirements for Performance Year 2020

In the CY 2021 PFS proposed rule, we explained that as part of the March 31st COVID–19 IFC, we made updates to the Part C and Part D Star Rating Systems for 2021 and 2022 based on concerns that the PHE for COVID–19 would pose significant challenges and safety concerns in successfully completing the CAHPS survey. In the March 31st COVID–19 IFC, we noted that many of the survey administration protocols could not be completed remotely, requiring staff to work in mail facilities and call centers where telephone interviewers assemble in close quarters to perform the telephone administration of the survey. Accordingly, to be in compliance with social distancing, travel bans, quarantine, and promoting health and safety of all involved in CAHPS data collection, we amended regulations in parts 417, 422, and 423 to eliminate requirements for collection of CAHPS data for performance year 2020 (85 FR 19271 and 19272).

In order to maintain consistency with the public safety determinations made in the March 31st COVID–19 IFC with respect to the CAHPS survey that is used in the Part C and Part D Star Ratings Systems, as noted above, and to address concerns about the negative impacts of COVID–19 on sample size and performance scores, we proposed to modify our regulations to remove the requirement that ACOs field a CAHPS for ACOs survey for performance year 2020. Instead, we proposed that ACOs would automatically receive full credit for each of the CAHPS survey measures within the patient/caregiver experience domain for performance year 2020. We acknowledged that the proposal would be retroactive for performance year 2020. However, section 1871(e)(1)(A) of the Act allows for retroactive application of a substantive change when the failure to apply the change retroactively would be contrary to the public interest. Based on the concerns described in the proposed rule, we concluded it would be in the public interest not to require ACOs to field the CAHPS for ACOs survey. Accordingly, we proposed to amend § 425.500(d) to add language stating that for performance year 2020 we would waive the CAHPS for ACOs reporting requirement and would automatically give all ACOs full credit for the CAHPS for ACOs survey measures (85 FR 50252 through 50254).

We sought comment on the proposal to waive the CAHPS for ACOs reporting requirement and to give ACOs full credit for the CAHPS for ACOs survey measures for performance year 2020. The following is a summary of the comments we received and our response.

Comment: A majority of commenters supported our proposal to waive the CAHPS for ACOs reporting requirement for performance year 2020 and to provide ACOs automatically with full credit for each of the CAHPS survey measures. Commenters pointed to inadequate sample size, an inability to generalize results of the survey due to safety measures implemented during the PHE for COVID–19, reduction of burden on Medicare ACO beneficiaries, and concerns that paper surveys were not a sanitary choice for gathering feedback, as reasons why they supported our proposal. Only one commenter urged CMS to require ACOs to participate in the CAHPS for ACOs survey in a pay-for-reporting capacity for PY 2020 or to at least encourage interested ACOs to voluntarily participate in the survey. The commenter explained that without the CAHPS for ACOs survey, ACOs will be unable to capture the experience of patients during the PHE for COVID–19, as well as continue internal performance improvement efforts.

Response: We appreciate the support for our proposal to remove the CAHPS for ACOs survey reporting requirement for performance year 2020 and to give ACOs automatic full credit for each of the CAHPS survey measures. We acknowledge the commenter's concern with regard to ACOs' inability to capture the experience of patients during the PHE for COVID–19; however, we note that outside of the Shared Savings Program requirements, each ACO is at liberty to determine if it wants to continue with the administration of the CAHPS for ACOs survey. Therefore, we are finalizing our proposal to waive the CAHPS for ACOs reporting requirement for performance year 2020 and to assign all ACOs automatic credit for each of the CAHPS survey measures within the patient/caregiver experience domain. We are adopting the proposed amendments to § 425.500(d) without modification.

2. Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

In the March 31st COVID–19 IFC (85 FR 19267–68), we noted that we would consider whether the current extreme and uncontrollable circumstances policy under which we assign an ACO the higher of the mean quality score across all ACOs and the ACO's own quality score, in the event the ACO is determined to be impacted by an extreme and uncontrollable circumstance would continue to be appropriate for PY 2020 and beyond. We explained that any change to that current policy would be made through future notice and comment rulemaking. While we did not propose any specific changes to the extreme and uncontrollable circumstances policy for PY 2020 in the March 31st COVID–19 IFC, we did receive public comments in response to both the March 31st COVID–19 IFC and the May 8th COVID–19 IFC regarding the impact of the PHE for COVID–19 on quality reporting and quality performance for PY 2020. The following is a summary of the comments we received in response to both the March 31st COVID–19 IFC and the May 8th COVID–19 IFC and our response.

Comment: Many commenters urged CMS to make all ACO quality measures pay-for-reporting for PY 2020. Several of the commenters who suggested this approach stated that the current extreme and uncontrollable circumstances policy was better suited for focal disasters, such as hurricanes or floods. The commenters explained that as a result of the PHE for COVID–19, ACO participants have faced, and will continue to face, numerous challenges during 2020, such as prioritizing care

for COVID–19 patients, canceling in-person preventative and chronic condition management visits to prevent the spread of the virus, and supplying personal protective equipment for the safety of healthcare providers and patients. Commenters stated that a move towards pay-for-reporting for 2020 would provide ACOs and their participating providers and suppliers the flexibility to respond to the PHE for COVID–19 while continuing to monitor and report these metrics. One commenter noted that the quality of care and patients' experience of care is as important as ever during these unprecedented times and encouraged CMS to continue to collect quality measure data as feasible and appropriate in 2020. The commenter explained that making quality measures pay-for-reporting in PY 2020 would ensure that an ACO's quality score does not adversely impact its financial performance due to factors outside of the ACO's control, such as COVID–19 related shifts in care delivery sites and staffing, deferred routine care, and increased telehealth utilization. The commenter stated that reverting quality scores to pay-for-reporting would also help to offset the anticipated deflationary impact of deferred care on the PY 2020 benchmark, which would lower the total amount of savings available to Shared Savings Program ACOs. Another commenter explained that pay-for-reporting for PY 2020 is warranted because, for the remainder of 2020, hospitals, group practices, and individual healthcare providers will be focused almost exclusively on urgent or emergent patients, as well as protecting themselves, their staff, and other patients from the coronavirus. One commenter stated that some measures would be difficult to satisfy if patients are not engaging with their healthcare providers in office or via telehealth and that, the restriction on elective procedures could make it difficult for patients to get their breast cancer, colon cancer, and various other screenings. The commenter noted that this problem could get worse if there is a resurgence of COVID–19 in the fall.

For various reasons, many commenters asserted that the current extreme and uncontrollable circumstances policy, which assigns an ACO the higher of the mean quality score across all ACOs and the ACO's own quality score, is insufficient for PY 2020 and beyond. One commenter explained that given the massive shifts in care delivery sites and staffing, increased telehealth utilization, data collection challenges and other COVID–19 related impacts in 2020, the application of either an average quality score or an individual ACO's own quality score based on data from the 2020 performance year is neither feasible nor appropriate. Other commenters expressed concern that the current extreme and uncontrollable circumstances policy is insufficient to mitigate the vast impacts of the PHE for COVID–19 on ACO quality performance because many ACOs are deploying their quality improvement staff to provide clinical care and assist in triaging patients, detracting them from their more typical quality improvement and care coordination work. These commenters explained that while there is value in ACOs' reporting what data they can during this challenging time, ACOs should not be held accountable to typical quality performance standards during this highly irregular PHE for COVID–19.

Several commenters expressed concerns about whether ACOs could meet the quality reporting requirements for PY 2020 because of the shift to providing services via telemedicine. One commenter stated that while CMS has expanded telehealth coverage for Medicare beneficiaries, several quality measures cannot be properly met in a remote setting such as immunizations and mammography screening, which are services that can only be performed in person. Another commenter requested that CMS allow patient-reported information provided during telehealth visits to satisfy quality measures where applicable. The commenter explained that per the quality measure specification for HTN–2 (NQF 0018)(ACO–28): Controlling High Blood Pressure, only blood pressure readings performed by a clinician or a remote monitoring device are acceptable for numerator compliance with this measure and that CMS does not permit information reported or taken by the member. The commenter noted that Medicare beneficiaries may be reluctant to have an in-person office visit and may not have access to a remote monitoring device, as described in the measure specification, and their information may not be available for use in determining the ACO's performance on the measure.

Other commenters suggested that CMS should allow ACOs to continue quality reporting efforts when possible, but that CMS should hold the ACOs harmless for any performance changes. Several commenters explained that it would not be appropriate to compare performance during 2020 to quality benchmarks established based on performance in previous years because the avoidance of care by patients and the postponement of certain critical services to preserve PPE will have lasting effects on quality. These commenters stated that they believe that ACOs will struggle to manage patients with chronic conditions and to provide proper preventive care during this time because patients are avoiding primary care, well visits, chronic care maintenance, and other health services. For these reasons, these commenters encouraged CMS to exclude 2020 quality performance data from future quality benchmarking. One commenter suggested that CMS mirror past Shared Savings Program performance rates and essentially grade on a curve for 2020. The commenter explained that the quality benchmarks should be adjusted so that the average Shared Savings Program quality score mirrors the average Shared Savings Program quality score in 2018. The commenter stated that this approach would keep the focus on quality and allow CMS to use quality performance to differentiate among ACOs in 2020, but would not unfairly transfer savings from ACOs to CMS due to difficulties in maintaining high rates of performance on quality measures (particularly routine preventative measures) during the PHE for COVID–19.

For PY 2021 and beyond, several commenters urged CMS to continue to study the impact of the PHE for COVID–19 on ACO quality performance in the months and years to come, as it is likely that additional policy changes will be necessary in the future. Other commenters encouraged CMS to consider how to mitigate the long-term impact of the PHE for COVID–19 on quality performance and stated that it might be necessary to modify quality measures that have narrow timelines for performance and to reset the measure targets in future years. One commenter suggested that CMS should commit to ongoing reevaluations of the Shared Savings Program and the other APMs it operates to adjust for any changes in patient risk and resource use in future financial and quality measurement methodologies. Another commenter requested that CMS collaborate closely with ACOs and health systems across the country to monitor and address the impacts of the PHE for COVID–19 on clinical quality and quality measure benchmarks in future performance years.

Response: We appreciate the feedback from commenters and we understand that there are myriad concerns related to quality reporting and quality performance for performance year 2020. However, we believe that ACOs should

be in a position to report CMS Web Interface measures for performance year 2020 beginning in January 2021. All ACOs were determined to be impacted by the PHE for COVID–19, which was declared during the quality reporting period for performance years starting in 2019. Yet, 98.7 percent of ACOs completely reported CMS Web Interface measures for 2019, including all 65 ACOs that were also impacted by a natural disaster during 2019 or the quality reporting period. We want to encourage reporting for performance year 2020 while still being cognizant of the impacts that the PHE for COVID–19 could have on quality reporting and quality performance. Accordingly, we do not believe that it is necessary to make performance year 2020 a pay-for-reporting year. Rather, we believe that maintaining our current extreme and uncontrollable circumstances policy, coupled with giving ACOs automatic full credit for the CAHPS for ACOs survey measures, offers appropriate relief to ACOs for performance year 2020, while still incentivizing ACOs to fully and completely report the remaining measures. All 10 CAHPS for ACOs survey measures are in one of the four domains used to calculate an ACO's quality performance score. This means 25 percent of an ACO's quality performance score for performance year 2020 would come from receiving full credit on the CAHPS for ACOs survey measures. In addition, each of the other three domains has at least one or more measures that is pay-for-reporting in performance year 2020, resulting in over 50 percent of the measures (14 out of 23) being assigned full points if the ACO completely and accurately reports quality data. Furthermore, because there is at least one measure in each domain for which ACOs would receive full points provided they completely report quality data, ACOs in their second or subsequent performance year would achieve the minimum attainment level on at least one measure in each domain as required under § 425.502(d)(2)(iii) to be eligible to share in any savings. We believe this may address some of the concerns expressed by stakeholders about the impact of the PHE for COVID–19 on 2020 quality performance. We also believe it is in the public interest to encourage ACOs to report quality data because ACOs could otherwise share in any savings earned without being held accountable for the quality of care that they provide to the more than 11 million beneficiaries who receive care through Shared Savings Program ACOs. In addition to incentivizing the reporting of quality of care measures, we believe it is critical to incorporate ACO performance on those measures into quality performance scoring for performance year 2020 in a meaningful way that also considers the impact of the current PHE for COVID–19.

Although we did not propose any specific modifications to the extreme and uncontrollable circumstances policy for performance year 2020 in the CY 2021 PFS proposed rule, we did solicit comment on a potential alternative approach to scoring ACOs for performance year 2020. The potential alternative modification we considered would be similar to the current policy for scoring quality performance under the extreme and uncontrollable circumstances policy, but would use the higher of an ACO's 2020 quality performance score or its 2019 quality performance score for ACOs that completely report web interface data for 2020. For new ACOs that completely report, we would continue to score them as pay-for-reporting and assign a quality score of 100 percent. ACOs that do not complete quality reporting would receive the 2020 ACO mean quality score as provided in § 425.502(f)(2).

Specifically, we solicited comments on the following potential modifications to the extreme and uncontrollable circumstances policy for performance year 2020:

(1) If an ACO in a second or subsequent performance year completely and accurately reports the CMS Web Interface measures for performance year 2020, the ACO will receive the higher of its performance year 2020 ACO quality performance score that would include automatic full credit for the CAHPS for ACOs survey measures, or the score used in 2019 for purposes of financial reconciliation. For re-entering ACOs that terminated in their second or subsequent agreement period, the ACO would receive the higher of its most recent prior ACO quality performance score or its 2020 quality performance score.

(2) If an ACO in a second or subsequent performance year or a re-entering ACO that terminated in its second or subsequent agreement period does not completely and accurately report the CMS Web Interface measures for performance year 2020, the ACO will receive the 2020 ACO mean quality performance score.

(3) If an ACO in its first performance year in the program or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period completely and accurately reports the CMS Web Interface measures, it will receive a quality performance score of 100 percent that reflects automatic full credit for the CAHPS for ACO survey measures.

(4) If an ACO in its first performance year or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period, does not completely and accurately report the CMS Web Interface measures for performance year 2020, it will receive the 2020 mean ACO quality performance score.

We received public comments on this potential alternative approach to scoring ACOs under the extreme and uncontrollable circumstances policy for performance year 2020. The following is a summary of the comments we received and our response.

Comment: While many commenters supported the alternative approach of assigning the higher of the ACO's 2019 or 2020 quality scores for ACOs that report quality, they explained that they considered this a ''fallback option'' and that they would prefer CMS to convert all measures to pay-for-reporting for performance year 2020 due to the impact of the PHE for COVID–19.

Response: The intent of the Shared Savings Program extreme and uncontrollable circumstances policy is to mitigate any negative impact of an extreme and uncontrollable circumstance on an ACO's quality performance or ability to report quality data to CMS and the resultant effect on financial reconciliation due to emergency circumstances outside of the ACO's control. As discussed above, given the high percentage of ACOs that completely reported CMS Web interface measures for 2019, we believe that ACOs should be in a similar position to report CMS Web Interface measures for performance year 2020 beginning in January 2021. While we understand commenters' concerns about the potential adverse impacts of the PHE for COVID–19 on quality reporting and quality performance scores, more than half of the measures in the Shared Savings Program quality measure set are pay-for-reporting for all ACOs for performance year 2020, which is higher than in previous years. We appreciate commenters' feedback on the potential alternative approach to scoring ACOs under the extreme and uncontrollable circumstances policy for performance year 2020. After careful consideration, however, we believe that our current extreme and uncontrollable circumstances policy, in addition to giving ACOs automatic full credit for the CAHPS for ACOs survey measures, will mitigate the negative effects of the

PHE for COVID–19 on quality performance for performance year 2020. Accordingly, pursuant to the current regulation at § 425.502(f)(2), ACOs will have their quality performance score set to equal the mean quality performance score for all Shared Savings Program ACOs for performance year 2020. However, if an ACO completely and accurately reports all CMS Web Interface measures during the quality reporting period, we will use the higher of the ACO's quality performance score for performance year 2020 or the mean quality performance score for performance year 2020 for all Shared Savings Program ACOs to calculate the ACO's quality performance score.

3. Change to Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy Provision Adopted in the March 31st COVID–19 IFC

As noted previously in this section, in the March 31st COVID–19 IFC, we modified the Shared Savings Program extreme and uncontrollable circumstances policy as it applies to disasters that occur during the reporting period to eliminate the restriction that the extreme and uncontrollable circumstances policy applies only if the reporting period is not extended (85 FR 19267 through 19268). The PHE for COVID–19 was declared during the quality reporting period for performance years starting in 2019 and it applied to all counties in the United States. As we explained in the March 31st COVID–19 IFC, we believed that it was appropriate to offer relief under the Shared Savings Program extreme and uncontrollable circumstances policy to all Shared Savings Program ACOs that were unable to completely and accurately report quality for 2019 by the extended deadline due to the PHE for COVID–19. We explained that this policy needed to be effective starting with the quality reporting period for performance years starting in 2019 to provide relief for Shared Savings ACOs who needed to focus resources on patient care during the PHE for COVID–19. Further, we acknowledged that, as illustrated by the current PHE for COVID–19, there could be unanticipated situations in the future, during which extension of a quality reporting window alone would not provide sufficient relief from reporting burden at a time when ACOs and their ACO providers and suppliers need to focus on patient care. Accordingly, in the March 31st COVID–19 IFC, we amended the regulation at § 425.502(f) to remove the phrase ''if the quality reporting period is not extended,'' effective for quality reporting for performances years starting in 2019.

We received public comments on modifying the extreme and uncontrollable circumstances policy as it applies to disasters that occur during the reporting period for performance years starting in 2019 to eliminate the restriction that the extreme and uncontrollable circumstances policy applies only if the reporting period is not extended. The following is a summary of the comments we received and our response.

Comment: Commenters were supportive of providing relief to all ACOs during the reporting period for performance years starting in 2019 by eliminating the restriction that the extreme and uncontrollable circumstances policy applies only if the reporting period is not extended. Commenters stated that this was a thoughtful approach to addressing the quality submission challenges resulting from the PHE for COVID–19 and welcomed this change. One commenter stated that they appreciated the acknowledgment by CMS that the previously issued 30-day extension of the PY 2019 quality reporting period alone was insufficient relief from the reporting burden for ACOs and their ACO providers/suppliers during this public health emergency. Another commenter noted appreciation for this approach, explaining that a number of physicians may be unable to submit quality data in a timely manner due to the demands on their practices associated with the PHE for COVID–19.

Response: We thank commenters for their positive feedback. We are finalizing, without modification, the revisions that were made to the regulation at § 425.502(f) in the March 31st COVID–19 IFC to remove the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended.

J. Removal of Selected National Coverage Determinations

In the CY 2021 PFS proposed rule (85 FR at 50255), we proposed to use the notice and comment rulemaking to identify and remove older NCDs that we believed no longer contained clinically pertinent and current information or no longer reflected current medical practice. We explained that eliminating an NCD changes a substantive legal standard related to Medicare coverage and payment under section 1871(a)(2) of the Act because items that were covered nationally under Title XVIII would no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, in the absence of an NCD, the coverage determinations for those items and services would be made by Medicare Administrative Contractors (MACs). We also noted that if the previous NCD barred coverage for an item or service under title XVIII (that is, national noncoverage NCD), a MAC would now be able to cover the item or service if the MAC determined that such action was appropriate under the statute. Removing a national non-coverage NCD may permit access to technologies that may be beneficial for some uses. We explained that as the scientific community continues to conduct research producing new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions. In the proposed rule, we also described the circumstances that we had used in determining whether an older NCD should be removed.

We sought public comments that may identify other reasons for proposing to remove NCDs. We also noted that we were interested in whether the time-based threshold of ''older''—which had been designated as 10 years—continued to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time would be more appropriate.

We also described two previous times that we used an expedited public process for removing NCDs. The proposals and final decisions related to these removals are located in the Medicare Coverage Database, available at *https://www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=7&mcdtypename=Expedited+Process+to+Remove+National+Coverage+Determinations&bc=AgAAAAAAAAAAAA%3d%3d&*.

As discussed in the proposed rule, we continue to recognize the need to periodically review our policies and processes to ensure that we remain effective and efficient as well as open and transparent. We noted that we are aware that clinical science and technology evolve and that items and services that were once considered state-of-the-art or cutting edge may be replaced by more beneficial technologies or clinical paradigms. Additionally, proactively removing obsolete broad non-coverage NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. In light of the Supreme Court's decision in *Azar* v. *Allina Health*

Services, 587 U.S. ___, 139 S. Ct. 1804 (2019)), we have determined it would be appropriate to use the notice and comment rulemaking procedures described in section 1871(a)(2) of the Act to remove outdated or unnecessary NCDs.

In Table 37 of the proposed rule, we listed the NCDs that we proposed to remove and described the mechanisms by which we identified NCDs for consideration. We solicited comment on the nine NCDs discussed in Table 41, as well as comments recommending other NCDs for CMS to consider for future removal. In the CY 2021 PFS proposed rule, we summarized each of the nine NCDs and provided a rationale for removal for each one. NCDs are listed in the Medicare National Coverage Determinations Manual located at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961*.

TABLE 41: Proposed NCDs for Removal

NCD Manual Citation	Name of NCD
20.5	Extracorporeal Immunoadsorption (ECI) using Protein A Columns (01/01/2001)
30.4	Electrosleep Therapy
100.9	Implantation of Gastroesophageal Reflux Device (06/22/1987)
110.14	Apheresis (Therapeutic Pheresis) (7/30/1992)
110.19	Abarelix for the Treatment of Prostate Cancer (3/15/2005)
190.1	Histocompatibility Testing
190.3	Cytogenetic Studies (7/16/1998)
220.2.1	Magnetic Resonance Spectroscopy (09/10/2004)
220.6.16	FDG PET for Inflammation and Infection (03/19/2008)

In summary, we solicited comment on the proposals to remove each of the nine NCDs, as well as comments recommending other NCDs for CMS to consider for future removal. Additionally, we solicited public comments that may identify other reasons for proposing to remove NCDs. We solicited comments on whether the time-based threshold of ''older'' which was designated as 10 years in the 2013 notice continues to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time is more appropriate. We requested commenters include a rationale to support their comments. We noted that we will use the public comments to help inform our decision to take one of three actions on the nine NCDs proposed for removal:

- Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.
- Retain the current policy as an NCD.
- Reconsider the NCD. We also noted that comments suggesting that the NCD should be revised, rather than eliminated, should include previously unreviewed evidence in order to support a change in national coverage.

We received more than 100 public comments on the proposed removal of selected NCDs, the process for identifying NCDs for removal, as well as the vehicle for removing NCDs. The following is a summary of the comments we received and our responses.

Comment: Many commenters generally supported the proposal to periodically identify and remove NCDs that are no longer clinically relevant or are infrequently used and appreciated CMS seeking input from stakeholders. Commenters agreed with agency efforts to ensure that NCDs are based on current scientific evidence, are relevant to the Medicare population and some acknowledged that the Medicare coverage process is designed to provide greater contractor flexibility. Many also agreed with using rulemaking for removing outdated NCDs as a transparent way to gather input from stakeholders and ensure beneficiary access to services.

Response: We thank commenters for their support for periodically removing outdated NCDs and for their support for using rulemaking.

Comment: Several commenters noted that CMS should have other options for retirement of NCDs that do not include notice and comment rulemaking. One commenter stated that rulemaking does not provide enough flexibility for CMS to retire obsolete NCDs upon receipt of clinical data demonstrating that the NCD is no longer appropriate. Another commenter disagreed with CMS' legal interpretation of Supreme Court's decision in *Azar* v. *Allina Health Services,* 587 U.S. ___, 139 S. Ct. 1804 (2019), and suggested that the statute provides for CMS to remove outdated NCDs through an expedited administrative process such as the process we described in 2013 (78 FR 48164). The commenters also noted that CMS should have a process that is nimble and flexible and requested that CMS finalize a policy that allows retirement of NCDs through a subregulatory process similar to the 2013 expedited subregulatory administrative process.

Response: We do not agree that section 1871(a)(2) of the Act would permit the removal of multiple NCDs at one time through a subregulatory process. While not legally binding on the public, NCDs establish controlling coverage policies for particular items and services for Medicare contractors and adjudicators in the Medicare appeals process, § 405.1060, and establish substantive legal standards related to coverage and payment. Given the importance of NCDs in notifying the public when particular items or services will (or will not) be covered under Title XVIII of the Act, we believe that a public process is necessary to remove those controlling policies. We note that Congress has separately established a public comment process in section 1862(l) of the Act, to be used in making NCDs and that NCDs are expressly exempt from the rulemaking requirements in section 1871(a)(2) of the Act. While the statute does not establish a specific process for removing NCDs, using the process required by section 1871(a)(2) of the Act is appropriate when changing a substantive legal standard governing the scope of benefits or payment for services. This result is consistent with the Supreme Court's

decision in *Azar* v. *Allina Health Services,* 139 S. Ct. 1804 (2019).

Comment: A few commenters questioned whether we will now be using rulemaking for NCD reconsiderations in addition to removals and whether we will create new NCDs through rulemaking. One commenter questioned if an NCD specifies coverage and non-coverage for multiple indications under the NCD, would this process be used to remove non-covered indications under the NCD. The commenter also questioned how would CMS address situations when a specific non-coverage portion of the NCD could be considered for removal.

Response: We thank commenters for their questions and the opportunity to clarify. As noted above, section 1871(a)(2) of the Act contains an exception for NCDs, and we are not required to use rulemaking procedures to establish or change a particular NCD. We will continue to use the NCD procedures established by section 1862(l) of the Act and that include an opportunity for public comment to reconsider or revise particular NCDs, as explained in the August 7, 2013 **Federal Register** notice (78 FR 48164). We proposed to use rulemaking to remove multiple old NCDs at one time, which would be more efficient than reconsidering each NCD separately.

Comment: A few commenters questioned whether CMS will use this process to remove and/or ''wrap up'' Coverage with Evidence Development (CEDs) as well as NCDs, given that CEDs are part of an NCD.

Response: We may consider using the removal process for CED NCDs in the future, but we note that none of the NCDs we proposed for removal at this time are CED NCDs.

Comment: Some commenters stated that CMS should rarely or never remove NCDs, but should retain and update them, optimizing appropriate use of NCDs rather than minimizing their use. Several commenters noted that CMS should only remove NCDs that provide for broad non-coverage, such as for items and services once considered experimental. These commenters noted that NCDs that provide even limited coverage for certain indications act as a floor and should be either retained or updated instead of allowing coverage determinations to be made at the local level.

Response: We believe it is in the best interests of the Medicare program and Medicare beneficiaries to regularly evaluate both coverage and broad-noncoverage NCDs because medical science may change over time. When we identify outdated NCDs or stakeholders bring them to our attention, we use our discretion either to reconsider and update the NCD as appropriate or to propose to remove the NCD if appropriate to allow the coverage determination to be made by the local MACs. Removing outdated NCDs in some cases can remove barriers to innovation and can pave the way for a robust local determination. This flexibility will allow stakeholders to provide new evidence for our consideration to support either reconsideration or the removal of an outdated NCD. We do not agree that it is always in the best interests of beneficiaries to keep old NCDs as a coverage floor; there are instances when NCDs are outdated and the practice of medicine has changed to the extent that some covered indications are obsolete or potentially create coverage barriers if the information is no longer current.

When we evaluate particular NCDs for removal, we take into account information gathered from stakeholders, the claims data for those items and services, and factors such as whether there may be documentation requirements within the NCD that are outdated and create a barrier to coverage. The rulemaking process will provide an opportunity to consider public input before the NCD would be removed. We could decide to retain those NCDs after considering public comments.

Comment: One commenter suggested that CMS should collect quality data collected as a part of an NCD in order to evaluate and maintain quality care, particularly related to new technology, previously unstudied populations.

Response: We thank the commenter for the suggestion about incorporating quality data into NCDs, though it is outside the scope of this proposal. Because there are many different quality programs established by the Medicare Act, it is difficult to evaluate in the abstract whether data collection through NCDs would be consistent with the existing statutory and regulatory requirements.

Comment: Several commenters opposed removing NCDs, either generally, or with regard to specific NCDs in this rule, because they believed that Medicare Advantage (MA) Plans are not required to follow LCDs created by MACs. The commenters noted removing NCDs that provide for coverage or limited coverage will create access barriers for MA plan enrollees because they noted the MA plans will choose not to continue covering those services.

Response: We appreciate the commenters' concerns, but believe there are sufficient beneficiary protections in place. Medicare Advantage plans (MA) are required to cover all Part A and Part B benefits for their enrollees, subject to limited exclusions such as for hospice care and kidney acquisition costs. The MA program regulation at 42 CFR 422.101(b) requires, and has required since the inception of the MA program, MA plans to comply with the written coverage determinations (that is, LCDs) of the local Medicare contracts (that is, the MACs) in the geographic area where the MA plan provides coverage (63 FR 34986, 35077). Section 1852(a)(1)(C) of the Act provides MA plans with the option to comply with the LCD that provides the more beneficial coverage to the plan's enrollees in cases where the MA plan service area includes more than one LCD area. All of this is further explained in the Medicare Managed Care Manual, Chapter 4, section 90, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.*

Comment: In response to our solicitation for public comments about other reasons that may support the removal of an NCD, a number of commenters support the continued use of the factors that CMS has used in removing outdated NCDs since 2013. Other commenters identified other factors that might be relevant for CMS to consider. One commenter stated that CMS needs to be more flexible and nimble in responding to changes in the standard of care and that the only criterion for removal should be presentation of sufficient clinical data to CMS to support retirement of an NCD irrespective of how old it is. The requestor recommended that CMS provide examples of what amount and type of information and clinical data would be ''sufficient'' to support removal. The commenter proposed an example of evidence-based professional society guidelines with a grade of evidence of A or B as sufficient to demonstrate whether an NCD should, and therefore could, be retired. Another commenter recommended that CMS assess and propose applying criteria similar to those under other Medicare programs, including for Medicare Part D.

Response: We appreciate the commenters that supported the use of the factors that CMS had previously used in identifying outdated NCDs. We will continue to consider those factors as modified by the additional public suggestions. We also agree with the commenter that suggested we pay attention to the changes in the standard of care, and that some NCDs may need to be removed in those circumstances regardless of age. We will consider

changes in the standard of care in making these determinations. We also agree that changes in evidence-based professional society guidelines with a high grade of evidence could be a good example of information that may support removal of an NCD in some circumstances. In order to be more flexible and nimble, we do not intend to establish an exclusive list of criteria as decisions may depend on the particular changes in medical practice at the time. We are grateful for the helpful public suggestions.

Comment: One commenter questioned whether the 10-year timeframe of ''older NCDs'' is tied to the last effective date or to the NCD's original implementation date. They also questioned how CMS will consider NCDs that are greater than the 10-year timeframe, but have been updated to address clinical changes affecting the services.

Response: To determine the age of NCDs we had used the effective date of the NCD, which, for some NCDs is the same date as the final decision memorandum was released. For determining the age of an NCD that has been reconsidered since the initial NCD was published, the clock restarts whenever a NCD reconsideration is conducted. For example, if we have an NCD for a particular service that was effective February 5, 2009, but was reconsidered in 2016 with an effective date of October 30, 2016, we would consider the NCD to be 4 years old.

Comment: We received many comments and recommendations on the 10-year threshold for identifying older NCDs for further evaluation for potential removal. A number of commenters stated that a specific threshold age, like 10-years, is arbitrary and does not reflect the rapid evolution of medical care in this century, and that age of the NCD should be a rule of thumb and not a categorical restriction. Several commenters stated that in many cases, even if an NCD is less than 10 years old, other evidence will be available that strongly suggests the NCD has most likely become outdated—such as when new and innovative therapies are released that substantially undermine core assumptions of an older NCD. While some commenters generally supported a definition of age at 10-years, we also received a wide variety of recommendations for timeframes ranging from annual review with 10 years as a maximum age, to reviewing NCDs at 3 years, 5 years or 7 years. Several commenters recommended that CMS adopt a shorter threshold and add a clinical evidence exception. These commenters stated that it would be appropriate to allow for the retirement of a NCD that is more than 5 years old, or a more recent NCD if there is new clinical evidence or FDA approval that causes the NCD to be outdated or to restrict beneficiary access to medically necessary items and services. One commenter noted that using 10 years as a look-back period may not be long enough for some items and services that have longer adoption timelines, or that may not be superseded by newer items and services.

Response: We appreciate commenters' thoughtful recommendations. Commenters are correct that the 10-year factor was a general guideline to identify groups of potentially outdated NCDs for further evaluation for possible removal. We also could decide to retain the NCD or reconsider the NCD if the NCD needed to be substantively changed. We acknowledge the rapid pace of medical technology development and changes in standard of care and/or clinical evidence may occur more rapidly than every 10 years, and we will consider those factors as well as we evaluate whether existing NCDs should be removed.

Comment: We received several comments supporting removal of each of the following NCDs: NCD 30.4 Electrosleep Therapy, NCD 100.9 Implantation of Gastrointestinal Reflux Devices, and NCD 220.2.1 Magnetic Resonance Spectroscopy. We also received several comments supporting removal of NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns, some including recommendations for corresponding changes to the claims processing instructions for this service related to removal of the NCD. We also received no comments for NCD 110.19 Abarelix for the Treatment of Prostate Cancer.

Response: We thank commenters for their support and will finalize the removal of each of the 5 NCDs identified above as proposed. We note that we received no comments opposing removal of these specific NCDs. We appreciate the recommendations for corresponding changes to the claims processing instructions and we will consider them as we implement the removal of NCDs. We note that while the change in policy will be effective on the effective date of the final rule, implementing the change for NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns requires changes to national coding systems. The implementing Change Request (CR) will take the time discrepancies between effective and implementation dates into consideration and ensure claims are adjudicated appropriately retroactive back to the effective date of the NCD (in this case, the final rule).

Comment: We received a number of comments supporting removal of NCD 110.14 (Apheresis). Some commenters acknowledged that the NCD was outdated and does not currently reflect advances in apheresis medicine and patient care applications. Several commenters noted their previous support for removing the NCD when we last proposed its removal in 2015. Several expressed their intention to work together with other professional societies to educate the Medicare Administrative Contractors on the intricacies of apheresis care based on the current professional society guidelines.

We also received several comments opposing removal of the apheresis NCD because they believe the NCD—while very outdated— remains relevant and the NCD provides predictability of coverage for indications currently listed in the NCD. The commenters expressed concern that allowing MACs to determine coverage could create inconsistencies in coverage and could reduce access for beneficiaries across Medicare and other payers. Several commenters encouraged CMS to ensure that any changes to NCDs support flexibility, innovation, and patient care.

Response: We thank commenters for their thoughtful and informative feedback, both in support of removing the NCD and for maintaining it. Since commenters shared multiple viewpoints on this issue, we will take more time to consider the specific issues raised by commenters and will not finalize removal of this NCD in this final rule. We will continue to engage with stakeholders on the issue and will consider whether to propose the NCD for removal in next year's PFS proposed rule.

Comment: One commenter supported removing NCD 190.1 (Histocompatibility Testing). The commenter noted their belief that local contractors should have the flexibility to cover not only conventional HLA cross-matching but also other techniques that have been developed and that are emerging. Several commenters did not support removing the NCD and requested that CMS retain or retain and update the NCD to expand the covered indications. While recognizing that it is very outdated, the commenters stated it provides predictability regarding coverage of histocompatibility testing for kidney and other types of transplant care, and other conditions. Several commenters requested that CMS closely monitor local contractor activity to ensure there is no disruption in access

and coverage for current critical applications if CMS decides to remove this NCD.

Response: We appreciate commenter's thoughtful responses. Since commenters shared multiple viewpoints on this issue, we will take more time to consider the specific issues raised by commenters and will not finalize removal of this NCD in this final rule. We will continue to engage with stakeholders on the issue and whether to propose the NCD for removal in the CY 2022 PFS proposed rule.

Comment: One comment supported removing NCD 190.3 (Cytogenetic Studies) stating that ''the NCD is decades old, and laboratories now are able to detect and locate specific DNA sequences on a chromosome using diagnostic techniques that did not exist or were not widely available when the NCD was issued, including next generation sequencing and fluorescence in situ hybridization (FISH).''

Several commenters did not support removing the NCD and requested that CMS retain or retain and update the NCD because while recognizing that it is very outdated, they believe the NCD remains relevant as cytogenetic studies are in widespread use, and provides predictability of coverage, avoiding potentially disparate local coverage policies. Several requested that CMS update the NCD to remove outdated terminology that is now considered offensive. Commenters also stated that cytogenetic studies have not been replaced by Next Generation Sequencing (NGS), but that the tests are used in conjunction. One commenter mentioned that multiple professional guidelines and practice resources exist that support use of cytogenetic studies. Several commenters requested that CMS closely monitor local contractor activity to ensure there is no disruption in access if CMS decides to remove this NCD.

Response: We thank commenters for pointing out that genetic sequencing is commonly used in conjunction with cytogenetic studies. Since commenters shared multiple viewpoints on this issue, we will take more time to consider the specific issues raised by commenters and will not finalize removal of this NCD in this final rule. We will continue to engage with stakeholders on the issue and will consider whether to propose the NCD for removal in next year's PFS proposed rule.

Comment: We received many comments supporting removal of NCD 220.6.16 (FDG PET for Inflammation and Infection) and allowing local contractor discretion to determine coverage for this service. A number of these comments raised a concern about language in NCD 220.6 (Positron Emission Tomography (PET) Scans) that provides for non-coverage, ''. . . that a particular use is noncovered unless this manual provides that such use is covered.'' Commenters requested that CMS also revise NCD 220.6 to ensure that local contractors can make coverage determinations for FDG PET for Inflammation and Infection. Commenters also requested that CMS revise this language to expand coverage and allow for MAC discretion to cover PET for existing and new uses beyond inflammation and infection, to include any non-oncologic condition that falls within an FDA approval and is not currently non-covered by an NCD. A number of commenters offered drafts of revised language for the manual as well as current literature as support.

Response: We will finalize removal of the NCD as proposed, and will modify the NCD manual to ensure that contractors have the authority to make a coverage determination when claims are submitted for PET for Inflammation and Infection. We will ensure MAC discretion is available by making two revisions in the NCD manual. First, we will revise the NCD manual at section 220.6.16 (FDG PET for Inflammation and Infection) to remove the current NCD language and replace it with the following statement of local contractor discretion: ''Effective January 1, 2021, CMS determined that no national coverage determination (NCD) is appropriate at this time for FDG PET for Inflammation and Infection. In the absence of an NCD, coverage determinations for FDG PET for Inflammation and Infection will be made by the Medicare Administrative Contractors (MACs).'' In addition, we will also make a non-substantive conforming change to NCD 220.6 (Positron Emission Tomography (PET) Scans, to add the following sentence to the note section: ''Effective for dates of service on or after January 1, 2021, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for FDG PET for Infection and Inflammation (formerly NCD 220.6.16).'' We are making the conforming change to make it abundantly clear in both sections of the manual that contractors will make the section 1862(a)(1)(A) of the Act determination for this PET indication.

While the change in policy will be effective on the effective date of this final rule (January 1, 2021), implementing this change requires changes to national coding systems and to the NCD manual. The implementing CR will take the time discrepancies between effective and implementation dates into consideration and ensure claims are adjudicated appropriately retroactive back to the effective date of the NCD (in this case, the final rule).

With respect to the request to revise NCD 220.6 to remove the non-coverage language and expand availability of PET for non-oncologic indications at MAC discretion, that revision would require a reconsideration of the NCD that is beyond the scope of this rulemaking. We note the process for submitting a formal reconsideration request is described in the August 7, 2013 **Federal Register** notice (78 FR 48164) and are outlined on the Medicare Coverage page at *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD*. These sources include the factors for considering a request to be complete as well as the electronic and mail methods for submitting a complete, formal request.

Comment: Commenters recommended additional NCDs for future removal including: NCD 10.5 Autologous Epidural Blood Graft, NCD 90.1 Pharmacogenomic Testing for Warfarin Response, NCD 150.10 Lumbar Artificial Disc Replacement (LADR), NCD 160.22 Ambulatory EEG Monitoring, NCD 210.3 Screening Computed Tomography Colonography (CTC) for Colorectal Cancer, and NCD 240.6 Transvenous (Catheter) Pulmonary Embolectomy. We note that NCDs 10.5, 210.3, and 240.6 each were recommended for removal by a number of commenters. In addition, one commenter requested that CMS revise NCD 210.12 Intensive Behavioral Therapy for Obesity to expand the eligible providers that are able to offer IBT to patients with obesity.

Response: We thank commenters for their recommendations of NCDs for us to consider removing in the future. While we do not accept these comments as complete, formal requests, we will take the suggestions under advisement for future review and will continue to communicate with interested stakeholders. As noted above, the process for submitting a request for reconsideration is described in the 2013 **Federal Register** notice and is outlined on the Medicare Coverage page at *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD*.

With respect to the request to reconsider the eligible providers for NCD 210.12, that request is outside the scope of the proposed rule, but we note that interested parties may make a formal request for reconsideration following the process outlined at the website above.

Comment: We received a number of general comments, concerns and suggestions for reforming the NCD and LCD processes used in making coverage determinations.

Response: We thank stakeholders for their comments and suggestions, but those comments are outside the scope of the proposed rule.

After considering the comments, we are not finalizing removal of NCD 110.14 Apheresis, NCD 190.1 Histocompatibility Testing, and NCD 190.3 Cytogenetic Studies. We will take more time to consider the specific issues raised by commenters regarding these NCDs and will consider whether to propose them for removal in next year's PFS proposed rule. We are finalizing removal of six NCDs as proposed, including NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns, NCD 30.4 Electrosleep Therapy, NCD 100.9 Implantation of Gastrointestinal Reflux Devices, NCD 220.2.1 Magnetic Resonance Spectroscopy, and NCD 220.6.16 FDG PET for Inflammation and Infection. Local Medicare contractors will determine coverage under section 1862(a)(1) of the Act for those specific items or services previously addressed through the NCDs. We will remove all six NCDs on the effective date of the final rule. However, changes in coverage require an implementation process in order to make required changes in manual guidance as well as coding/coverage/payment system edits for the items and services. While it typically takes a number of months to implement a change in coverage, the implementing CR will take the time discrepancies between effective and implementation dates into consideration and ensure claims are adjudicated appropriately retroactive back to the effective date of the final rule.

K. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. SUPPORT Act Requirements

Section 2003 of the SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. Section 2003 of the SUPPORT Act requires that the Secretary use rulemaking to specify circumstances and processes by which the Secretary may waive the EPCS requirement and provides the Secretary with authority to enforce and specify appropriate penalties for non-compliance with EPCS. The SUPPORT Act specifies some circumstances under which the Secretary may waive the electronic prescribing requirement with respect to controlled substances that are covered Part D drugs and also permits HHS to develop other appropriate exceptions. The circumstances that are listed in the statute under which the Secretary may waive the EPCS requirement are at section 1860D–4(e)(7) of the Act, as added by section 2003 of the SUPPORT Act, and include:

- A prescription issued when the practitioner and dispensing pharmacy are the same entity;
- A prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT 2017071 standard;
- A prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;
- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;
- A prescription issued by a practitioner prescribing a drug under a research protocol;
- A prescription issued by a practitioner for a drug for which FDA requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;
- A prescription issued by a practitioner—

++ For an individual who receives hospice care under this title; and

++ That is not covered under the hospice benefit under this title; and

- A prescription issued by a practitioner for an individual who is—

++ A resident of a nursing facility (as defined in section 1919(a)); and

++ Dually eligible for benefits under this title and title XIX.

2. Current Public Health Emergency (PHE)

On January 31, 2020, the Secretary determined that a PHE existed for the United States to aid the nation's health care community in responding to COVID–19 (hereafter referred to as the PHE for COVID–19). On March 13, 2020, President Trump declared the PHE for COVID–19. Effective October 23, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020 and July 25, 2020 that a PHE exists and has existed since January 27, 2020. Because of the PHE for COVID–19, and as the nation reopens, some individuals, such as those who are at high risk, may continue to practice self-isolation and social distancing.

We have implemented many regulatory and policy actions to swiftly aid the nation's healthcare system to effectively address the PHE for COVID–19. These actions include new flexibilities for telehealth and other electronic technologies [98] to ease the burden on providers and assure appropriate care in a range of settings for beneficiaries. Also, the DEA has adopted certain new temporary flexibilities to allow DEA-registered practitioners to prescribe controlled substances without having to interact in person with patients, effective for the duration of the PHE for COVID–19.[99] For example, during the PHE for COVID–19, DEA permits DEA-registered prescribers to issue controlled substance prescriptions to telemedicine patients who they have not seen in person under certain conditions, permits early refills of controlled substances permissible under state law, and allows prescribers to issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance. DEA's COVID–19 information page is available at *https://www.deadiversion.usdoj.gov/coronavirus.html.* The DEA has acknowledged the prevalence of paper prescribing and attempted to address some of the hardships it poses for prescribers and patients during the PHE for COVID–19.

[98] See *https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf.*

[99] See *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf.*

3. Electronic Prescribing of Controlled Substances (EPCS)

As discussed in the CY 2021 PFS proposed rule (85 FR 50074), we noted that social distancing is likely to be at least in part, responsible for the increase in EPCS during this PHE for COVID–19. In 2020, EPCS has increased to 50 percent of all prescription drug events (PDEs) for controlled substances being prescribed as compared to 38 percent in 2019.[100] With the use of electronic prescribing, once a patient and a provider have an established relationship, a medical visit can be conducted via telehealth and any necessary prescriptions can be electronically transmitted to the pharmacy without having to see each other in-person and risk transmitting COVID–19. Some insurers, including Part D plans, may be permitting medication refills, including for controlled substances, earlier than usual or for a more extended period of time than was previously allowed. Pharmacies that were not previously doing so may deliver medications, or deliver at no charge, and communities and individuals have worked together to design ways for vulnerable persons to continue to receive access to prescribed medications in tandem with these new government and private sector flexibilities.

EPCS provides multiple advantages over the traditional processing of paper prescriptions.[101] [102] [103] [104] [105] [106] In addition to improving workflow efficiencies, electronic prescribing of controlled substances can deter and help detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes. It can also provide more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions. By allowing for the direct transmission of electronic prescriptions between providers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. In addition, EPCS (dispensed medication) data is transmitted to Prescription Drug Monitoring Programs (PDMPs), which can help inform providers of patients' medication history and can aid in clinical decision making at the time of prescribing and/or before the medication, is dispensed by a pharmacy. It is also important to continue the assurance of privacy and security in the prescribing process, such as by controlling prescriber access through improved identity controls and authentication protocols. EPCS can also assure prescribers' identity more easily and may permit a single workflow for prescribing both controlled and non-controlled drugs, improving the overall prescribing process.[107]

From the patient standpoint, EPCS may reduce the logistical burden on patients who may otherwise be required to make multiple trips between providers and pharmacies to transport paper prescriptions when filling time-sensitive prescriptions while in pain or otherwise in need of medical treatment with controlled substances. EPCS can lessen the time needed to obtain prescriptions by minimizing trips to the physician to pick up paper prescriptions for refills and minimize transportation costs to and from the provider's office. EPCS identity and security requirements also assure prescribers, patients, and pharmacies that prescriptions are processed as intended. In addition to helping with the reduction in fraud previously described, EPCS minimizes the likelihood that prescriptions have been tampered with, since electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, which minimizes the likelihood of exposure to patients or other third parties. In the Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information issued on August 4, 2020 (85 FR 47151), we requested feedback on the appropriate waivers and whether CMS should impose penalties for noncompliance with the EPCS mandate in its rulemaking, and what should be the penalties. We plan to use the important public feedback we receive from the Request for Information in future standalone rulemaking.

In our proposed rule, we proposed to enact regulations requiring EPCS by January 1, 2022 to strike the balance between not placing too large of a burden on providers and helping ensure that the benefits of EPCS are leveraged expeditiously. Furthermore, we noted that requiring EPCS by January 1, 2022 would allow time to solicit and consider important feedback from the previously discussed Request for Information that is necessary for implementation of the EPCS requirements for waivers from the

[100] Based on Prescription Drug Event data processed through April 30, 2020.

[101] Phillips et. al. ''Market Guide for Identity Proofing and Corroboration.'' April 24, 2018. Gartner, Inc. Retrieved from *https://www.fedscoop.com/gartner-guide-identity-proofing-corroboration-2018/* on April 30, 2020.

[102] Ryan, D. ''FinCEN: Know Your Customer Requirements.'' February 7, 2016. Harvard Law School Forum on Corporate Governance. Retrieved from *https://corpgov.law.harvard.edu/2016/02/07/fincen-know-your-customer-requirements/#2b* on April 30, 2020.

[103] Nix, M. ''Five Questions: Ken Whittemore Talks Past, Present & Future of E-Prescribing Controlled Substances.'' March 31, 2020. SureScripts. Retrieved from *https://surescripts.com/news-center/intelligence-in-action/opioids/five-questions-ken-whittemore-talks-past-present-future-of-e-prescribing-controlled-substances?utm_campaign=IIApercent2FBlogpercent20Subscription&utm_source=hs_email&utm_medium=email&utm_content85955401&_hsencp2ANqtz-8xs36u7xTFZ-ieOxJk3309SApbE7to_fnk1SZvz2jqwz0pA3k7TtW9byiOq2zBlheLInMOeajCMCKeQUTzcEDP79HEaeXI52QiadhAYAWU3Px2eZc&_hsmi=85955401* on April 30, 2020.

[104] Zhang et. al. ''T2FA: Transparent Two-Factor Authentication.'' June 15, 2018. IEEE Access. Retrieved from *https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=8386653* on April 30, 2020.

[105] Konoth R.K., van der Veen V., Bos H. (2017) How Anywhere Computing Just Killed Your Phone-Based Two-Factor Authentication. In: Grossklags J., Preneel B. (eds) Financial Cryptography and Data Security. FC 2016. Lecture Notes in Computer Science, vol 9603. Springer, Berlin, Heidelberg. Retrieved from *https://link.springer.com/chapter/10.1007 percent2F978-3-662-54970-4_24* on April 30, 2020.

[106] Cal and Zhu. ''Fraud detections for online businesses: a perspective from blockchain technology.'' *Financial Innovation* (2016) 2:20. Retrieved from *https://link.springer.com/content/pdf/10.1186/s40854-016-0039-4.pdf* on April 30, 2020.

[107] HHS Office of the National Coordinator, The ONC Doctors' Perspective: Electronic Prescribing of Controlled Substances (EPCS) Is on the Rise, and We Must Work Together to Address Barriers to Use: *https://www.healthit.gov/buzz-blog/health-it/the-onc-doctors-perspective-electronic-prescribing-of-controlled-substances-epcs-is-on-the-rise-and-we-must-work-together-to-address-barriers-to-use.*

requirements and penalties. This included soliciting feedback from prescribers that we do not directly regulate under MA, and/or Part D, and who are not enrolled in Medicare or Medicaid. Section 1860D–4(e)(2)(E) of the Act requires the Secretary to adopt electronic standards for mandatory use by Part D plans. As stated above, the statute provides the Secretary with the authority to develop any exceptions to EPCS that may be warranted, and to enforce and specify appropriate penalties for non-compliance with the requirement. We noted that we do not have an existing process for imposing penalties on non-compliant prescribers for EPCS. In developing an entirely new penalty process, we must make sure that it enforces the new EPCS requirement, allows for exceptions only when needed, but does not reduce beneficiaries' access to needed drugs. Separate from this rule, we noted that we intend to conduct future standalone rulemaking that would address these topics.

Based on these considerations, we proposed to amend 42 CFR 423.160(a) by adding the requirement that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances covered under the Medicare prescription drug program using the NCPDP SCRIPT 2017071 standard by January 1, 2022, except in circumstances in which the Secretary waives the requirement. We proposed that prescribers would be required use the NCPDP SCRIPT 2017071 standard because they are already required to use this standard when conducting e-Prescribing for covered Part D drugs for Part D eligible individuals, and we noted that we believe that prescribers should use the same standard for their electronic prescribing of controlled substances.

We also solicited comments regarding the impact of the proposal on overall interoperability and the impact on medical record systems. Finally, we solicited comments on whether the change would be significant enough for a January 1 implementation date, which is required for all significant changes affecting Part D plans.

We received 57 timely public comments in response to this proposed provision. We have summarized these comments and our responses below.

Comment: A majority of commenters supported our proposal requiring that prescribers use the NCPDP SCRIPT 2017071 standard for EPCS prescription transmissions within the Part D program. Commenters echoed their support for many of the reasons set forth in our proposed rule including the increased security of the transmission of the prescription and reduction of the number of callbacks from pharmacists seeking to clarify handwritten prescriptions.

Response: We thank commenters for their support. In light of the overwhelming majority of commenters supporting this proposal, we are finalizing the requirement that prescribers use the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances covered under Medicare Part D.

Comment: A few commenters opposed e-Prescribing of controlled substances because they believed that EPCS would allow prescriptions to be written by a doctor electronically without seeing the patient. One commenter stated that such practices would lead to an increase in the opioid epidemic in our country.

Response: The assumption that electronic prescribing means inappropriate prescribing is an incorrect one. In order for a prescription to be covered under Part D, it must be a valid prescription according to applicable federal and state laws. Under DEA rules,[108] a prescription must be issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or a covering practitioner in general. Therefore, implementation of EPCS standard should not have an adverse impact on the appropriateness of controlled substances distributed.

Comment: Most commenters addressed our proposal to implement the EPCS requirement by January 1, 2022. A few commenters requested CMS to adhere to the January 1, 2021 date specified in the SUPPORT Act because of the many safety benefits associated with EPCS articulated in the rule. These commenters included Part D sponsors, companies involved in processing e-Prescribing transactions and most, but not all, pharmacies. A few commenters noted that there is an absolute and urgent need to implement section 2003 of the SUPPORT Act by the January 1, 2021 deadline in the statute even if the requirement is not enforced. A commenter stated that they understood that CMS does not believe it will be able to enforce this requirement on prescribers starting in January 2021, so proposed that CMS implement the requirement in mid-2021. Another option presented by the commenters was for CMS to make the rule effective January 1, 2021 but decline to enforce it until some later date. They stated that just having the rule in force would encourage EPCS and cited evidence from state experiences to support this position.

Comments from nearly all prescribers indicate that implementation of EPCS by 2021 would not be feasible. For example, a large system commented that they had planned to implement EPCS by 2021 but were forced to reprioritize human and financial resources to support their colleagues and the patients and families impacted by, the PHE. Several other commenters stated that an EPCS mandate for a 2021 implementation date would undoubtedly cause some prescribers to simply stop prescribing controlled substances as part of their practice and this could inadvertently create patient suffering and harm.

Some prescriber groups supported the proposed January 1, 2022 date, while others requested even more time for implementation. They expressed appreciation for the flexibility that CMS has provided for providers struggling with the challenges of the current PHE and the difficulties they are facing implementing new systems or upgrades. Some commenters noted that there are both cost and implementation efforts required to install EPCS and with the COVID–19 pandemic, physicians face financial and operational hardships which create burden upon those who need to install EPCS functionality. Several commenters expressed views that the delay is prudent and will allow additional time for providers impacted by COVID, rural providers, and small practices to install and become familiar with EPCS. The specific challenges listed by these commenters include upgrading EHR software in a short timeframe, implementing dual authentication measures while social distancing, and paying the cost involved with system upgrades. One commenter noted that their software vendor was not making visits to their practice during the PHE, rendering software upgrades unfeasible.

Response: We appreciate the role that pharmacies, Part D plans and others have played in preparing for and advocating for EPCS. We understand that prescribers would prefer the proposed January 1, 2022 effective date and appreciate concerns raised by commenters about having adequate time to implement EPCS. However, as stated in our proposed rule, approximately 98 percent of pharmacies in the US are ready to accept EPCS, and Part D plans that have been reporting electronically

[108] See Title 21, § 1300.04(3)(f) available at *https://www.deadiversion.usdoj.gov/21cfr/cfr/1300/1300_04.htm.*

to CMS have no concerns about their readiness.

We also believe there are many benefits to EPCS that outweigh commenter concerns regarding readiness. EPCS can help deter and detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes. It can also help avoid data entry errors and pharmacy calls to a prescriber to clarify written instructions. By allowing for the direct transmission of electronic prescriptions between providers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. In addition, EPCS (dispensed medication) data is transmitted to Prescription Drug Monitoring Programs (PDMPs), which can help inform providers of patients' medication history and can aid in clinical decision making at the time of prescribing and/or before the medication is dispensed by a pharmacy. From the patient standpoint, EPCS may reduce the logistical burden on patients by lessening the time needed to obtain prescriptions, by minimizing trips to the physician to pick up paper prescriptions for refills, and by minimizing transportation costs to and from the provider's office. In addition, EPCS has important safety benefits in that it minimizes the likelihood that prescriptions have been tampered with. Because electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, this minimizes the likelihood of exposure to patients or other third parties. We believe that an earlier effective date would encourage more timely implementation of EPCS in Part D, and therefore, bring these important benefits of EPCS faster to Part D prescribers, patients, and the Part D program.

Regarding the concern that the January 1, 2021 implementation date may cause prescribers to stop prescribing necessary controlled substances, we understand that this may be an issue. In light of this concern, as well as other potential implementation issues, we plan on monitoring the PDE data to look for concerning prescribing patterns, so we can adjust the program accordingly. Due to the PHE, we also seek to mitigate concerns about the impact that the January 1, 2021 deadline would cause by establishing a compliance date in addition to the effective date that would allow prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 to still be considered compliant.

In consideration of the benefits of EPCS and in light of the comments received, we are modifying our proposal by finalizing this provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022. With a January 1, 2022 compliance date, prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the requirement. We believe that this phased approach strikes a balance of adhering to the timeframe set forth in the SUPPORT Act, supporting more rapid implementation of EPCS, and giving prescribers adequate time to comply with the EPCS implementation requirement.

Comment: Several commenters mentioned the health care provider costs involved in implementing EPCS. One commenter recommended that CMS work with ONC to ensure that the cost of implementing the part D electronic prescribing standard is taken into account when EHR's are evaluated in accordance with one of ONC's EHR certification criteria, and to ensure that EHR developers cannot charge additional fees for building in this prescribing standard capability into their certified products. Accordingly, the commenter requested that HHS take steps to minimize the cost of EPCS requirements to physician practices. Another commenter stated that their practice has delayed implementing EPCS due to the need to upgrade their EHR software, which has proven to be costly. The commenter stated that given the pandemic impact that amount is now unaffordable for their small primary care practice. Another commenter acknowledged that EPCS implementation costs can be high, but that a prudent buyer of software support can find less expensive options.

Response: We share concerns about high health care provider costs associated with implementing EPCS, particularly during the PHE. However, neither ONC nor CMS have the authority to dictate EHR vendor charges for implementing electronic prescribing capabilities that would meet EPCS criteria. We encourage those who provide software solutions to support EPCS to make their products as accessible as possible. As prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the EPCS implementation requirement, software providers will have more time to review their costs, and providers will have more time to evaluate and choose among available options.

Comment: One commenter noted that even with a delayed compliance date, not all practices or providers are currently using or planning to use this technology due to practice style, size, resources, capability and willingness to adopt new technology. The commenter stated that if modernization is required, alternative options should be available, or assistance should be provided to ease the burden of cost and implementation.

Response: We recognize the difficulties that many providers may have in implementing an EHR or eRx that accommodates EPCS. However, the aforementioned benefits of EPCS, especially in light of current social distancing guidelines, outweigh the burden of implementing an EHR or eRx system for EPCS. Furthermore, based on our conversations with the industry and analysis, CMS believes that once the EHR and eRx systems are implemented, the burden of EPCS will be less than the current manual process.

Comment: Several commenters recommended CMS work with other federal entities that are involved in eRx rules including ONC and the DEA.

Response: We will continue to coordinate with our Federal partners and will continue to coordinate EPCS efforts to the extent possible based on our individual legal mandates.

Comment: One commenter suggested CMS clarify whether the EPCS requirement will apply to inpatient settings as well.

Response: Section 2003 of the SUPPORT Act mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be conducted electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. The proposal that we are finalizing includes all providers who prescribe medications that are Schedule II, III, IV, or V controlled substances that are covered Part D drugs. This generally includes medications dispensed in outpatient pharmacies but may also include medications dispensed to a patient who is being discharged to the home from an inpatient or emergency room setting, a long term care setting, or a Medicare hospice, or who is receiving care in a patient's home.

Comment: One commenter encouraged CMS to provide technical assistance and resources for clinicians in order to streamline this transition.

Response: As EPCS is permitted in every state, and will soon be required in 31 states, many state agency websites and state medical boards provide excellent resources for physicians to use. The DEA, on its website, has also posted frequently inquired about questions related to EPCS that can serve as a helpful resource. As a result, we do not believe that we need to provide any other resources, since they would merely duplicate the information on the websites.

Comment: A few commenters raised concerns about the impact on beneficiaries who have to receive prescriptions electronically rather than via traditional paper prescriptions. One commenter speculated that EPCS would interfere with the patient's pharmacy choice. Others voiced concern that patients may want a paper prescription in hand so they can visit multiple pharmacies and compare prices. The commenter noted that e-Prescribing may harm cancer patients who may benefit from receiving prescriptions from their physicians where the likelihood of adherence and quality improvement increases.

Response: Given that nearly all US pharmacies are ready to accept electronic prescriptions of controlled substances, this means that a prescriber can use EPCS and send the prescription where the patient instructs. We also recognize that the price of a given medication may impact a beneficiary's pharmacy choice. However, EPCS is being implemented in the Part D program at a time when patients and providers will have access to electronic real time benefit tools that can offer price transparency without requiring in person visits or calls to alternate pharmacies for price checking. As required in the May 2019 final rule (84 FR 23851), which updated the Part D e-Prescribing standards, each Part D plan is required to adopt one or more prescriber real time benefit tools that are capable of integrating with at least one prescriber's e-Prescribing system or electronic health record no later than January 1, 2021. We encourage patients and providers to use these tools. We are unaware of any evidence to indicate that the act of a physician handing a prescription to a patient has a positive impact on medication adherence.

Comment: One commenter expressed concern with the health care provider burden associated with reporting EPCS transactions to CMS.

Response: We clarify that there is no added provider burden associated with reporting EPCS transactions to CMS as the NCPDP Telecommunications standard captures the source of a prescription transaction through the prescription origin code. A value of ''3'' in field 419–DJ indicates that a prescription was transmitted electronically; such information is sent to the Part D plan which then conveys that information to CMS through PDE data. No additional action on the part of the prescriber is needed.

Comment: Some commenters questioned about complying with EPCS requirements when it is not reasonable or feasible. These circumstances include instances when NCPDP SCRIPT 2017071 does not support the prescription, systems downtime, lack of internet connectivity or when the patient needs a paper prescription to receive medication in advance of a vacation.

Response: There may be instances when a prescriber is unable to transmit a particular prescription electronically using the named SCRIPT standard. Under those circumstances, paper prescriptions are compliant with CMS requirements. The NCPDP SCRIPT Implementation Recommendations document provides guidance on implementing the standard. We remind commenters that we have issued electronic standards for use in Medicare Part D since the program's inception, and have withheld issuing compliance actions under circumstances such as a sporadic downtime or lack of internet access that the covered entity might experience. Consistent with this previous practice, we do not anticipate issuing compliance actions when a prescriber is unable to transmit a particular prescription electronically using the named SCRIPT standard under such circumstances.

Comment: A commenter suggested establishment of a list of mandated exemption codes and modifying existing NCPDP standards to enable tracking of paper prescriptions exemption codes Prescribers could then handwrite the exemption code(s) on paper prescriptions and/or input the codes in the EHR in notes or in a new custom field. Pharmacies would capture the exemption code(s) through use of the NCPDP telecom standard and convey the information to the payer and on to CMS through PDE data. They noted that this would take years to implement.

Response: We thank the commenter for the suggestion. The proposed solution seems to be one way of leveraging technology to capture information about why EPCS is not being used to transmit a given prescription. However, we would be concerned about the burden that required exemption coding might place on prescribers and pharmacies. Prescribers would have to know the appropriate code to use and enter it onto the paper prescription and pharmacies would have to look for, and enter the code into their dispensing systems in order to convey that information to Part D plans. It is also unclear how the Part D exceptions may/may not overlap with exemptions allowed under state EPCS rules, which could cause confusion. However, as the adoption of EPCS progresses, we would rely on the NCPDP to work with prescriber groups to examine the suggestion in detail. We believe some providers and pharmacies may embrace this mode of communicating why a paper prescription for controlled substances is used, while others may not. We also caution that the absence of such a code would not be a valid reason for a pharmacy not to dispense a medication nor for a Part D plan to deny payment for an otherwise valid written prescription. We look forward to hearing about any discussions about this concept as they progress.

Comment: One commenter requested CMS be specific in defining which NCPDP SCRIPT version 2017071 capabilities are expected to be used before a pharmacy or payer rejects incomplete prescriptions.

Response: Section 2003 of SUPPORT Act makes it clear that the EPCS requirement should not be construed as requiring a sponsor of a prescription drug plan under Part D or a pharmacist to verify that a practitioner, with respect to a prescription for a covered Part D drug, has a waiver from the EPCS requirement under Part D. Consistent with the statute, nothing in our rule should cause the dispensing pharmacy to reject a prescription nor the Part D plan to deny payment for an otherwise valid written, oral, or fax prescriptions that is consistent with laws and regulations. As a result, we do not believe it is our place to define which of the standard's capabilities should be used before the rejection of an incomplete prescription.

Comment: Several commenters expressed concerns that CMS' proposal assumes these functionalities to be successful, when in actuality they still require significant fixes and delayed implementation timelines. Perhaps the biggest challenge clinicians will face, commenters stated, is incorporating EPCS into their EHRs, and most clinician practices are not in a position to cover the costs and acquire the

necessary resources for technical or system upgrades required by EHR vendors—especially rural and small practices. Commenters stated that due to the COVID–19 pandemic, many practices have been forced to delay or cancel implementation altogether of EHRs that support EPCS due to the implementation cost. Commenters voiced the concern that practices that do not currently have the capability to prescribe electronically would be forced to purchase such a software. A commenter supported the intent to facilitate efficiency, convenience, and better security with the implementation of EPCS, but encouraged CMS to avoid unreasonable burden imposed upon clinicians and delay compliance until at least January 1, 2023.

Response: We are aware of the difficulties that clinicians may face when implementing EPCS. However, with potentially broad public health implications, we believe a January 1, 2021 effective date complies with the statutory intent and would enable the safety and other benefits previously discussed to be put in place during the current pandemic. However, in order to help ensure that the burden on prescribers is not unreasonable, we are finalizing a compliance date of January 1, 2022 such that prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the requirement.

Comment: Many commenters stated their intent to comment on the EPCS request for information. We received a number of comments that requested CMS address the need for exceptions to the EPCS rule and to set forth an overview of the penalties to be used. Some commenters provided comments with regard to waivers, health professionals and practices and their ability to declare a hardship and to be exempt from EPCS requirements; others requested exclusions for those who are unable to electronically prescribe controlled substances by January 1, 2022 for various reasons. A few commenters suggested that CMS explicitly clarify that the current exemptions at § 423.160(a)(3)(iii) will continue to apply for prescriptions of controlled substances where the sender and the beneficiary are part of the same legal entity. Those commenters stated such an exemption would align with CMS' existing policy at § 423.160(a)(1) regarding use of the NCPDP SCRIPT Standard because the prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals is not transmitted using electronic media, and previous clarifications CMS has issued as part of other electronic prescribing requirements. Commenters also stated that CMS should also align such an exception with CMS' existing policy at § 423.160(a)(3)(iii), which allows the use of HL7 messages for transmitting prescriptions and prescription-related information internally by clarifying that exemption's applicability to prescriptions for controlled substances.

Response: We thank the commenters for their feedback and will take all comments included in the Electronic Prescribing for Controlled Substances; Request for Information and comments received on the PFS proposed rule into account as we implement this program. The SUPPORT Act requires that CMS use rulemaking to determine any processes for enforcement, including on any prescriber waivers, penalties and appeals. CMS will continue to consider comments and recommendations received in response to both the proposed rule and the RFI and will propose any such processes in a future rule, to be effective no earlier than January 1, 2022. Based on detailed and thoughtful comments received in response to our proposed rule and the RFI, we understand that any future rulemaking may be better informed through additional inquiry, such as review of state EPCS program characteristics and insight gained from implementing the programs, consideration of the interactions between EPCS and PDMP workflows, and obtaining clarification of the implications of potential updates to the DEA's biometric standards for dual authentication on technical and workflow requirements. CMS will continue to review its own PDE data to better understand EPCS patterns across prescribers and provider groups and what this data can convey about the characteristics of Part D prescribers of controlled substances (such as geographic areas, specialties, and Part D prescribing volume and patient residence locations).

After consideration of the comments received, we are finalizing the provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022 to encourage prescribers to implement EPCS as soon as possible, while helping ensure that our compliance process is conducted thoughtfully.

L. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

1. Background

Medicare Part B covers drugs under a limited drug benefit that includes drugs and biologicals defined in section 1861(t) of the Act. Medicare Part B drugs and biologicals fall into three general categories: Drugs and biologicals furnished incident to a physician's services, drugs and biologicals administered via a covered item of durable medical equipment (DME), and other drugs and biologicals specified by statute. Payment amounts for most separately payable Medicare Part B drugs and biologicals are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on.

Drugs (not including biologicals or biosimilar biological products, as defined in section 1847A of the Act) paid using the methodology in section 1847A of the Act fall into two broad and mutually exclusive categories: Multiple source drugs and single source drugs. These terms are defined in statute and are further discussed in this section and the next section. In most cases the distinction between the multiple source drugs and single source drugs is fairly straightforward and is made as outlined in program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf*): The payment limit under section 1847A of the Act for that biological product or single source drug is based on the pricing information for products produced or distributed under the applicable FDA approval. However, for a subset of drug products approved through the pathway established under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the distinction is less straightforward.

The drug approval pathway established under section 505(b)(2) of the FFDCA has existed since 1984, before the ASP payment methodology was established. The section 505(b)(2) pathway is provided for applications that contain full reports of investigations of safety and effectiveness, where at least some of the information for an approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. An application submitted under section 505(b)(2) (which we refer to as a ''section 505(b)(2) application'') may

rely on FDA's finding of safety and/or effectiveness for a listed drug (an approved drug product) or published literature provided that such reliance is scientifically justified and the section 505(b)(2) applicant complies with the applicable statutory and regulatory requirements, including patent certification if appropriate. Unlike an Abbreviated New Drug Application (ANDA) for a generic drug, a section 505(b)(2) application is not required to have the same labeling as the listed (approved) drug(s) that the application relied upon. However, some drugs approved through the pathway established under section 505(b)(2) of the FFDCA (which we refer to as ''section 505(b)(2) drug products'') share significant portions of their FDA-approved labeling with the listed (approved) drug(s) that the application submitted through section 505(b)(2) relied upon, for example prescribing information on safety, efficacy, and pharmacokinetics. In some cases, the section 505(b)(2) drug product shares significant portions of labeling with generic drugs that are paid as multiple source drugs under section 1847A of the Act. Examples of situations where a section 505(b)(2) drug product shares similar labeling to listed (approved) products include a sterile injectable drug product that had been sold as a lyophilized powder in a vial and was then approved for sale as a concentrated liquid in a vial, as well as a ready-to-use IV bag.

The number of drugs approved through the pathway established under section 505(b)(2) of the FFDCA has been growing, from about 40 per year from 2011 to 2016, to about 60 in 2017, and 70 in 2018. Some of these approvals include drugs paid under Part B. Although we have assigned some section 505(b)(2) drug products to separate single source billing and payment codes, our payment approach for newly marketed section 505(b)(2) drug products, where an existing multiple source code descriptor describes the section 505(b)(2) drug product accurately, and where the active ingredient(s), the drug name, and portions of the prescribing information correspond to existing products that are assigned to and paid under a multiple source drug code, has been to assign the section 505(b)(2) drug products to the existing multiple source code. We believe that this approach, as described in more detail below, is consistent with statutory language in section 1847A of the Act. The definition of multiple source drug at section 1847A(c)(6)(C) of the Act states in part that for a multiple source drug, there are two or more drug products which are rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' also known as the Orange Book). For purposes of Part B drug payment under section 1847A of the Act, we interpret this to mean that if there is an existing HCPCS billing code that includes two or more drug products which are rated therapeutically equivalent and meets the remaining conditions of the definition of a multiple source drug, that billing and payment code is a multiple source drug code, and the section 505(b)(2) drug product meets the definition of a multiple source drug in section 1847A(c)(6)(C) of the Act. The statutory language in section 1847A(b)(3) and (6) of the Act provides discretion for CMS to assign additional drug products to a multiple source drug code. In other words, if a multiple source drug code exists, we are permitted to assign other multiple source drug products to that code for the purpose of payment as a multiple source drug under section 1847A of the Act. We note that if the drug product is described by a multiple source code, it meets the definition of multiple source drug at section 1847A(c)(6)(C) of the Act, and it does not meet the definition of a single source drug at section 1847A(c)(6)(D) of the Act, because the definition of a single source drug expressly excludes a multiple source drug in section 1847A(c)(6)(D)(ii) of the Act.

We assigned section 505(b)(2) drug products to existing multiple source drug codes for Part B payment under section 1847A of the Act in limited situations, that is, where an existing multiple source code descriptor describes the section 505(b)(2) drug product, the active ingredient(s) correspond to one another, the section 505(b)(2) drug product's labeling, particularly the prescribing information, includes information (such as the drug description, dosage and administration, pharmacokinetics, and indications) from other drug products that are paid under the multiple source drug code, and the section 505(b)(2) drug product can be used and prescribed in a manner similar to other products in the multiple source drug code. This information is used to determine whether the section 505(b)(2) drug product can be billed and paid using the existing multiple source drug code. The determination is based on the discussion in the previous paragraph, that is, if there is an existing HCPCS billing code that includes two or more drug products which are rated therapeutically equivalent and meet the remaining conditions of the definition of a multiple source drug, that billing and payment code is a multiple source drug code. Consistent with the statutory language in section 1847A(b)(3) and (6) of the Act, which provides discretion for CMS to assign additional drug products to a multiple source drug code, a section 505(b)(2) drug product can be assigned to the multiple source drug code. The section 505(b)(2) product assigned to the multiple source drug code meets the definition of a multiple source drug in section 1847A(c)(6)(C) of the Act. Thus, for the purpose of payment under Medicare Part B, the section 505(b)(2) drug product can be billed and paid under that existing multiple source code. However, in situations where there is no existing multiple source drug code that describes a section 505(b)(2) drug product, the section 505(b)(2) drug product is typically assigned to its own single source code.

2. Multiple Source Drug and Single Source Drug Codes

Section 1847A of the Act uses the terms drug and drug product. Consistent with the statutory definitions discussed at section 1847A(c)(6)(C) and (D) of the Act and program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf*), we have applied the terms multiple source drug and single source drug at the billing and payment code level, meaning that ''drug'' corresponds to a HCPCS or other applicable billing code and its descriptor, which typically includes the active ingredient(s) of the drug. The term ''drug product'' corresponds to individual packages of the drug as identified by the National Drug Code (NDC) or other applicable alternative identifier.

The terms multiple source drug and single source drug are defined, respectively, in section 1847A(c)(6)(C) and (D) of the Act. Section 1847A(c)(6)(C) of the Act states that multiple source drug means, for a calendar quarter, a drug for which there are two or more drug products which are rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''); are pharmaceutically equivalent and bioequivalent, as determined by the FDA; and are sold or marketed in the United States during the quarter. Section 1847A(c)(6)(E) and (F) of the Act establish conditions under which pharmaceutical equivalence and

bioequivalence are met. The definition of multiple source drug in section 1847A of the Act can be interpreted to mean that once a multiple source drug code exists—that is, once there are two or more drug products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent, and CMS has assigned them to a multiple source drug code—then a subsequent product of the same drug—that is, a product that corresponds to the multiple source drug code's descriptor—can be assigned to such code even if the subsequent drug product is not, itself, therapeutically equivalent, bioequivalent or pharmaceutically equivalent. This is because in this case, the drug is multiple source, meaning that there are two or more products which are rated as therapeutically equivalent of that drug, as evidenced by the fact that the existing products are already assigned to the multiple source drug code. Once a drug product is assigned to a multiple source drug code, the product would not be assigned to a single source drug code because the definition of single source drug at section 1847A(c)(6)(D)(ii) of the Act states, in part, that a single source drug is a drug which is not a multiple source drug. Thus, when assigning drug products to multiple source and single source drug codes for the purpose of payment under section 1847A of the Act, we consider whether the product is described by an existing multiple source drug code first, and if the product is assigned to an existing multiple source drug code, its payment allowance will be determined based on the volume-weighted average ASPs of all drug products assigned to the code, rather than based solely on its own ASP (for example under a new single source code).

Section 1847A(b)(3) and (6) of the Act provide that payment for multiple source drugs is determined for all drug products included within the same multiple source drug billing and payment code. For multiple source drugs, we calculate a volume weighted average sales price across all drug products assigned to a billing and payment code. This typically means that the ASP-based payment amount for a multiple source drug code includes generic and branded drug products within an individual code.

Consistent with section 1847A(b)(3) and (6) of the Act and our interpretation of the definition of multiple source drug in section 1847A(c)(6) of the Act, we assign certain section 505(b)(2) drug products to existing multiple source drug codes. We determine whether to assign section 505(b)(2) drug products to multiple source or single source drug codes by comparing information about the section 505(b)(2) drug product to the descriptors for existing multiple source codes to which the drug products may be assigned for the purposes of payment amount determinations under section 1847A of the Act, as well as information about products already assigned to that descriptor. This information includes the products' active ingredients and labeling, particularly the prescribing information and, if necessary, additional sources such as the FDA's Approval Summary Review, which is a part of the FDA's application review files and is available at *https://www.accessdata.fda.gov/scripts/cder/daf/*, and drug compendia. The FDA's Approval Summary Review can provide additional details about information that is found in the drug's labeling and prescribing information and other compendia can supplement the information that is found in labeling and provide information about off label use of a drug.

Our case by case determination about the assignment of certain section 505(b)(2) drug products to existing multiple source drug codes is based on the factors described in further detail in the bullet points below: First, the products' active ingredient(s), drug name and description; second, the products' labeling information; third, how they are ordered (prescribed) and used clinically. These factors are assessed as a whole, using the information (for example, active ingredient, labeling, compendia, and FDA Approval summary), to determine whether an existing multiple source drug code describes a section 505(b)(2) drug product and whether the product can be assigned to an existing multiple source drug code for the purpose of payment under section 1847A of the Act. The determination is based on the following:

- The active ingredient and drug name of the section 505(b)(2) drug product and other drug products in an existing multiple source drug code.
- The drug description and indications, particularly whether differences such as the salt form, additional ingredients, or uses exist.

The two bullet points above identify the section 505(b)(2) drug product and multiple source drug code and establish what is being compared so that the determination can proceed, if necessary. For example, if the active ingredients and drug names do not correspond, there would not be a reason to assign the section 505(b)(2) drug product to the multiple source drug code or to proceed further. We also note that the active ingredient of a drug is often included in the HCPCS code descriptor that is used to bill a drug product and to pay for it under section 1847A of the Act. The drug description is used, if necessary, to clarify what the actual active ingredient(s) are, whether there are minor differences, such as salt forms and other inactive ingredients that may affect how the product is used. This information may be helpful when considered with the information in the next two groups of bullet points as we consider labeling and uses of the drug products.

- The labeling information (and if necessary other material from sources such as the FDA's Application Review Files, including the FDA's Approval Summary Review, and drug compendia), particularly pharmacokinetics, indications, adverse reactions, drug interactions, contraindications, warnings, precautions and clinical studies.

The bullet point above allows us to determine whether the same information, for example the same studies, were used to support the approval of the section 505(b)(2) drug product and to gauge how much of the labeling information from existing multiple source drug products appears in the section 505(b)(2) drug product's labeling. This information also supports the determination in the next bullet point. The more labeling information that a section 505(b)(2) drug product has in common with drug products in an existing multiple source drug code, the more likely it is that the existing code describes the section 505(b)(2) drug product, such that CMS will assign it to that multiple source drug code for the purpose of payment under section 1847A of the Act.

- The dosage and administration, pharmacokinetics, indications, contraindications, warnings, drug interactions, and adverse reactions.

The bullet point above allows us to determine whether the section 505(b)(2) drug product is ordered and used in patient care in the same way as products assigned to a multiple source drug billing code. The dosage and administration, pharmacokinetics, and indications are particularly important because we consider whether a prescriber writes a prescription for the section 505(b)(2) drug product in the same way as drug products assigned to a multiple source drug code and whether the products could be used for the same uses. Typically, a prescription includes the following information: The drug, dose, route of administration, and frequency. The quantity of a drug (or duration of therapy) and refills are also

a part of a prescription, but are less of a factor for Part B where most drugs are used incident to a physician's services. Typically, drugs used incident to a physician's services are administered and billed as a very limited number of doses, often just one, are administered during a service, and the drug is not dispensed for the patient for use over an extended time period beyond an office visit or outpatient hospital visit. The elements in the bullet point reflect how a drug is used and administered in the care of patients and in turn determine how billing for the drug is accomplished; that is, whether an existing code descriptor describes a section 505(b)(2) drug product and can be used to bill for it.

As a simple example of our approach, if the active ingredient, dose, route of administration and frequency of the section 505(b)(2) drug product are the same as those for drug products in a multiple source drug code, then it is likely that an existing code descriptor describes a section 505(b)(2) drug product and can be used to bill for it. The information does not have to be an exact match, for example different uses of a drug product may require different doses, routes of administration, or frequencies. However, if the section 505(b)(2) drug product and the multiple source drug products in the existing multiple source drug code could both be used for the same indication (potentially by way of off-label use), then billing for both with the existing HCPCS code would still be feasible. In such situations, similarities between labeling information such as whether the same studies were used to establish pharmacokinetic parameters may factor into the assessment. In summary, the information discussed above is used as a whole to determine whether the existing multiple source drug HCPCS code descriptor describes the section 505(b)(2) drug product or if a new HCPCS code would be needed describe the product for payment under Part B.

The information described in the bullet points above is usually sufficient for our determinations, but from time to time we may reach out to the drug manufacturer, seek post marketing data, or review literature sources for additional information to assist us with understanding the information in the bullet points above and to assist with determinations in complicated situations, for example where indications vary, but it appears that the section 505(b)(2) drug product could still be used, administered and billed in the same manner as drug products assigned to an existing multiple source drug code.

We are aware that some section 505(b)(2) drug products are very different from previously approved products that may be used to support their approval. We do not assign all section 505(b)(2) drug products to existing multiple source drug codes. In circumstances where an existing code does not describe the section 505(b)(2) drug product and use of the existing code would not be suitable for billing and payment of the section 505(b)(2) drug product under Part B based on the assessment described above, the section 505(b)(2) drug product would not be assigned to the existing multiple source drug code. The following examples illustrate how we distinguish section 505(b)(2) drug products that are assigned to an existing multiple source drug code from those that are not. If a section 505(b)(2) drug product has the same active ingredient, same dose and dosing interval, and prescribing information and includes the same clinical studies (for example, the same patient number, same response rates and same adverse reaction frequencies) as drug products assigned to an existing multiple source drug code, the section 505(b)(2) drug product would be assigned to the multiple source code. However, if the section 505(b)(2) drug product has different pharmacokinetics, for example if it is a sustained release version of a drug that permits less frequent dosing compared to drug products in an existing multiple source drug code, or if the section 505(b)(2) drug product has additional active ingredients not found in the drug products in an existing multiple source drug code, the section 505(b)(2) drug product would not be described by the existing multiple source drug code. As a result, it would not be considered a multiple source drug under section 1847A(c)(6)(C) of the Act because there would not be at least two drug products for that drug that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent; thus, the section 505(b)(2) drug product would be considered a single source drug and typically assigned to a single source drug code.

3. Codifying Existing Policy for Section 505(b)(2) Drug Products

As we stated in the CY 2021 PFS proposed rule (85 FR 50264 through 50265), our approach (described in section II.L.2 of this final rule) for the payment of section 505(b)(2) drug products has been in place for at least 12 years, and it is also consistent with the concept of paying similar amounts for similar services. It is based on the definitions of multiple source drug and single source drug in section 1847A(c)(6)(C) and (D) of the Act and authority to assign drug products to billing and payment codes in section 1847A(b)(3) and (6) of the Act as discussed in the sections above. We explained that a number of section 505(b)(2) drug products that are described by an existing multiple source drug code are priced significantly higher than comparable products. Two recently introduced section 505(b)(2) drug products that appear to be comparable to drug products in existing multiple source drug codes (using the approach described in the section earlier) have Medicare payment allowances that are approximately 10 times higher than that of the existing multiple source code. We stated that we believe that assigning section 505(b)(2) drug products that are described by existing multiple source drug HCPCS codes to those existing HCPCS codes is consistent with efforts to curb drug prices while limiting opportunities to ''game the regulatory process and the patent system in order to unfairly maintain monopolies.'' [109] We stated that we believe our approach also encourages competition among products that are competitors—that is, when they are described by one billing code and share similar labeling.

We stated our concern about high payments for section 505(b)(2) drug products if they are assigned to unique separate HCPCS codes despite being described by existing multiple source drug codes. We also stated our concern about the effect of high payment amounts on individual beneficiaries' cost sharing payments for these products.

Therefore, for these reasons, in the CY 2021 PFS proposed rule (85 FR 50265) we proposed to codify our long-standing process for assigning certain section 505(b)(2) drug products to existing multiple source drug codes if the section 505(b)(2) products are described by existing multiple source drug codes consistent with our interpretation of the definition of multiple source drug in section 1847A(c)(6)(C) of the Act and the approach described above. Specifically, we proposed that where a section 505(b)(2) product is not itself therapeutically equivalent, pharmaceutically equivalent, or bioequivalent, as determined by FDA, to another drug product, we would nonetheless consider it to meet the definition of multiple source drug if, based on an assessment of its active ingredient, labeling, compendia, and

[109] *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.*

other information, the product is described by the code descriptor for an existing multiple source drug code. That is, we would assess the section 505(b)(2) drug product's active ingredient(s), drug name, and description, whether the section 505(b)(2) drug product's labeling, particularly the prescribing information, includes information from other drug products that are paid under the multiple source drug code, and whether the section 505(b)(2) drug product is used and prescribed in a manner similar to other products in the multiple source drug code, in order to determine whether the section 505(b)(2) drug product is described by an existing multiple source drug code. We would not assign all section 505(b)(2) drug products to multiple source codes and would not assign section 505(b)(2) drug products to a single source drug code exclusively made up of single source drug products. We stated that we would also reevaluate and potentially revise previous payment (and coding) decisions to maintain consistency with our proposed approach, if finalized. Consistent with these proposals, we also proposed to revise the definition of multiple source drug in regulation text at § 414.902 by amending the regulation text to state that multiple source drugs may include drug products described under section 505(b)(2) of the FFDCA and adding § 414.904(k) that describes the framework for our determination as discussed in this section of the preamble.

4. Summary of Comments

The following is a brief summary of comments we received on these proposals. More detailed comments and responses follow this summary. We received approximately 37 timely comments on section 505(b)(2) drug products. In general, commenters, primarily manufacturers, stated that the proposal was contrary to the statute, conflicted with FDA's therapeutic equivalence ratings, would impair access for patients, underpay providers, and dampen innovation. Several comments from beneficiary advocate and provider groups generally repeated the same points, although some comments expressed support for curbing drug prices, particularly if the proposal did not affect patient access. Several comments appeared to take a middle ground that conditionally supported the proposals, particularly if more detail could be provided and if effects on patient access were considered. Several commenters supported the proposals without conditions.

Comment: Several commenters contended that CMS lacks the statutory authority to adopt the proposals in the proposed rule, and some stated that the proposal was not consistent with subregulatory guidance from 2007. These commenters stated that the language in the statute clearly defines multiple and single source drugs, that assigning non-therapeutically equivalent drug products to a multiple source code contradicts the plain language of section 1847A of the Act, and that CMS's proposal is contrary to Congress' intent. Commenters also stated that the definition of multiple source drug in section 1847A(c)(6) of the Act requires each drug product assigned to a multiple source code to be therapeutically equivalent, pharmaceutically equivalent and bioequivalent to another product in the code, and that the only exception is a provision (sometimes referred to as the grandfathering provision) under section 1847A(c)(6)(C)(ii) of the Act.

Response: We disagree that our proposed approach is inconsistent with the statute. The statute allows CMS to assign drug products to an existing multiple source code, and does not require that the code include only products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent to one another product. As outlined in the proposed rule, the definition of multiple source drug in section 1847A(c)(6)(C) of the Act can be interpreted to mean that once a multiple source drug exists—that is, once there are two or more drug products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent, and we have assigned them to a multiple source drug code—then a subsequent product of the same drug—that is, a product that corresponds to the multiple source drug's billing code descriptor—can be assigned to such code even if the subsequent drug product is not, itself, therapeutically equivalent, bioequivalent or pharmaceutically equivalent. In this case, the drug is already multiple source, meaning that there are two or more products of that drug which are rated as therapeutically equivalent, as evidenced by the fact that the existing products are already assigned to the multiple source drug code. Once a drug product is assigned to a multiple source drug code, the product would not be assigned to a single source drug code because the definition of single source drug at section 1847A(c)(6)(D)(ii) of the Act states, in part, that a single source drug is a drug which is not a multiple source drug. Also, we are not aware of any sources, such as Committee Reports that describe Congress' intent in detail, that conflict with our interpretation. The proposed approach focuses on assigning drug products to a drug code solely for Part B drug payment purposes and is consistent with the statutory definitions at section 1847A(c)(6)(C) and (D) of the Act. However, we do not agree that statutory language at section 1847A(c)(6)(C)(ii) of the Act about an exception is relevant to this discussion. This grandfathering provision applies only to ''single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003.'' The exception does not apply to multiple source drugs or the assignment of drug products to multiple source drug billing and payment codes.

The proposals are also consistent with the program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*). In the program instruction, we addressed how we would identify ''single source drugs'' and ''biological products'' using a multi-step process. We did not expressly address how we would identify multiple source drugs. The program instruction is not inconsistent with our proposal because in both cases, the determination of the ''drug'' is reflected at the HCPCS code level. In contrast, the term ''drug product'' corresponds to individual package sizes of the drug as identified by the NDC or other applicable alternative identifier. The proposals published in the CY 2021 PFS proposed rule add to, rather than conflict with, the 2007 program instructions and provide detail about how we approach Medicare Part B payment of section 505(b)(2) drug products.

Comment: A number of commenters stated that our approach is not consistent with or does not take into account FDA's ratings of therapeutic equivalency for drugs and the application of the ratings for interchangeability determinations pertaining to these products.

Response: We disagree with these comments. The therapeutic equivalence ratings published by FDA and its work associated with these ratings pertain to Part B drug payment only to the extent that they are used to define when two or more drug products are therapeutically equivalent, which is relevant to the determination of whether a drug is single source or multiple source as defined in section 1847A of the Act. FDA's therapeutic equivalence ratings do not themselves dictate payment under Medicare Part B.

Relatedly, our proposals for section 505(b)(2) drug products do not affect these ratings or this work; rather, our proposals apply only to drug payments under section 1847A of the Act. This is consistent with the different roles of FDA and CMS—the former assesses a drug product's safety and effectiveness, and the latter administers the Medicare program.

As we discussed in the previous comment response, one condition for meeting the definition of a multiple source drug at section 1847A(c)(6)(C) of the Act is that there be two or more drug products rated as therapeutically equivalent. However, a subsequent product of the same drug—that is, a product that corresponds to the multiple source drug code's descriptor—can be assigned to such code even if the subsequent drug product is not, itself, therapeutically equivalent. In other words, where there are two or more drug products that are rated as therapeutically equivalent in the Orange Book, the drug meets the definition of multiple source drug for purposes of Medicare Part B payment, and this has no bearing on any particular drug product's therapeutic equivalence rating. Where there is a multiple source drug (as defined in section 1847A(c)(6)(C)), other non-therapeutically equivalent drug products of that drug may be assigned to the HCPCS code for purposes of payment under section 1847A of the Act. Section 1847A of the Act does not mention interchangeability as a factor in determining payment for drugs, nor does it explicitly describe how multiple source drug products must be assigned to billing and payment codes or how they must be paid.

We also disagree with comments that our proposal fails to take product interchangeability into account. Payment under Medicare Part B and interchangeability are separate issues—the former pertains to when Medicare will pay for a product, and the latter pertains to drug dispensing and clinical decisions. In Medicare Part B, where most drugs are used incident to a physician's services and are not dispensed through a retail pharmacy, what a provider administers to a patient is often determined by the prescriber or where that prescriber practices. For example, due to space and inventory budget limitations, a physician's office will generally stock a limited range of drug products that are administered incident to a physician's services. Section 1847A of the Act does not specify which drug products physician must stock or provide, nor does it dictate how prescribers may utilize drug products in patient care. Interchangeability governs the range of products that a pharmacist may dispense to fill a prescription and also is not addressed in section 1847A of the Act. Rather, interchangeability and pharmacy substitution are typically addressed in State law and may be affected by factors such as hospital bylaws, inventory and other matters that are outside of CMS' purview. As noted previously, our proposals pertain only to payment under Medicare Part B, and do not purport to dictate which drug products a prescriber may prescribe or a pharmacy may dispense.

Comment: A few commenters noted that the assignment of section 505(b)(2) drug products to multiple source codes was new and had never been applied by CMS. However, other commenters acknowledged CMS' longstanding policy with respect to these drug products.

Response: We disagree with commenters that stated the proposals are a new policy that has not been applied to Part B drug payments. As we stated in the proposed rule, the policy has been in place for at least 12 years. For example, this process has been applied to gemcitabine injection products that were first marketed as Gemzar(R), a sterile lyophilized powder packaged in vials. The brand products were assigned to a HCPCS code (J9201), and once generic gemcitabine products were marketed, they also were assigned to J9201, making J9201 a multiple source drug code. Later, liquid concentrates of gemcitabine injection were approved through the pathway established under section 505(b)(2) of the FFDCA. These concentrated liquid products also were assigned to the existing multiple source HCPCS code, J9201, even though they were not, themselves, therapeutically equivalent to the branded products in J9201. Subsequently marketed lyophilized powder and concentrated liquid gemcitabine injections, as well as gemcitabine products approved under ANDAs also have been assigned to HCPCS code J9201.

ASP–NDC crosswalks that reflect these HCPCS assignments have been available to the public along with the quarterly ASP Drug Pricing files on the CMS website. We began including the concentrated liquid formulations in the ASP NDC crosswalks that were published for January 2012. The January 2012 Drug Pricing Files and the ASP NDC–HCPCS crosswalk are available in the Related Links section at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2012ASPFiles*. Although we do not describe the crosswalks as a complete listing of all NDCs used in pricing determinations, the crosswalks serve as a guide to help the public understand which products are included in the weighted average calculation for a given HCPCS code. The crosswalk files are readily available to the public via the CMS website and illustrate which NDCs are assigned to HCPCS codes for payment under section 1847A of the Act.

Comment: Several commenters discussed potential effects of the proposals on manufacturers. Commenters, primarily manufacturers that seek 505(b)(2) approvals for their products, expressed concerns that the proposals would dampen innovation, result in fewer drug approvals through the pathway, and contribute to a less efficient approval process, which could result in fewer choices for patients and prescribers and a less predictable marketplace. While some commenters expressed concerns about major effects on the industry and appeared to believe that all section 505(b)(2) drug products would be affected by the proposal, others suggested identifying situations where separate payment would be available in a predictable manner. Several commenters stated that if CMS moves forward with the proposal, CMS should exclude products with ''meaningful differences'' from the policy. One commenter encouraged CMS to continue an approach ''that allows for innovation, competition, and ultimately more therapeutic choices for Medicare beneficiaries.''

Response: As mentioned in the proposed rule, we are aware that the section 505(b)(2) pathway has been in existence since the 1980s, well before the implementation of the payment methodology in section 1847A of the Act. We are also aware of the potential advantages of seeking approval through the pathway established under section 505(b)(2) of the FFDCA compared to seeking approval under the section 505(b)(1) pathway. Under the 505(b)(1) pathway, the application contains full reports of investigations of safety and effectiveness that were conducted by or for the applicant or for which the applicant has a right of reference or use. Because the approval of a product through the section 505(b)(2) pathway relies on at least some information from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference, the use of the 505(b)(2) pathway can minimize time, effort and expense associated with bringing a product to the market, although some additional study of the product is typically

required. From experience with the crosswalking process (the assignment of NDCs to HCPCS codes for payment determinations under section 1847A of the Act), we have observed that section 505(b)(2) drug products are heterogeneous. Some of the products are very different from previously marketed products that were used to support the approval through the section 505(b)(2) pathway. For example, the section 505(b)(2) drug product may include additional active ingredients, or may incorporate formulation changes that result in significant changes to the dosing schedule (for example, changing from 3 times per day to once per day administration). However, some section 505(b)(2) drug products are very similar to drug products that are assigned to multiple source drug codes.

The application of our policy to determine assignment of section 505(b)(2) drug products to a multiple or single source drug code has resulted in the assignment of a limited number of these drug products to multiple source drug codes and under our proposal we anticipate that the number of assignments of drug products to multiple source codes would continue to be limited. Many section 505(b)(2) drug products are paid using single source drug codes under section 1847A of the Act. We have examined 23 instances associated with the assignment of section 505(b)(2) drug products to billing codes for payment under section 1847A of the Act during the years 2017 to 2019. Eighteen of the instances led to products being assigned to single source drug codes. Products associated with the remaining five instances were not priced as separately payable Part B drugs (for example, because payment is bundled with physician services). Seventeen of the 18 products that were assigned to single source drug codes are included in either the ASP Drug Pricing Files, OPPS Addendum B or both files (the exception is a product that was not yet marketed). These 17 products include an older antibiotic that was combined with a new ingredient that extended its antibiotic spectrum, a new formulation of a drug that is used in the treatment of opiate use disorder, and novel formulations of older drugs that are specifically designed for less frequent administration or are administered by a different route (such as a drug that was previously approved only as an oral drug and not paid under Part B, but was then approved as a section 505(b)(2) drug product as an injectable drug). Thus we believe that our policy has not led to the frequent assignment of section 505(b)(2) drug products with significant modifications (like an additional active ingredient) to multiple source drug codes. Further, if manufacturers continue to market products that one commenter described as having ''meaningful differences'' from multiple source drugs, we anticipate that section 505(b)(2) drug products approved in the future will not be assigned to multiple source drug codes frequently. For these reasons, we do not believe the commenters' concerns that the policy would have a major negative impact on innovation, access to products or the speed and efficiency of product approval are justified, nor would the policy discourage the use of the section 505(b)(2) pathway for drug approvals.

However, we have concerns about the consistency of how the policy has been applied recently. Of the 18 recently approved section 505(b)(2) drug products discussed above, we believe that two that were mentioned in the proposed rule should be reevaluated to determine whether they should be paid as single source or multiple source drugs. For example, a diluted and ready to administer IV bag of gemcitabine injection was recently approved (*https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208313Orig1s000TOC.cfm*). As discussed in a previous comment's response in this section, gemcitabine injection was originally sold as a lyophilized powder that is reconstituted and then further diluted for intravenous administration. Then concentrated liquids (which have to be further diluted before administration) were approved through the section 505(b)(2) pathway. The lyophilized powder, concentrated liquid and generic gemcitabine products are all assigned to HCPCS code J9201. Payment limits for this HCPCS code appear in the ASP Drug Pricing files and the various products appear in the corresponding ASP NDC–HCPCS crosswalk files; the October 2020 payment limit for HCPCS code J9201 for 2 grams of the drug, a commonly used dose, is $39.57. The newer gemcitabine injection product approved through the section 505(b)(2) pathway, which shares dosing, pharmacokinetics, adverse effect profile, and indications on labeling with the products assigned to J9201, but is packaged in a ready to administer IV bag, has a WAC (as reflected in pharmaceutical pricing compendia as of November 11, 2020) of $760 per 2 grams, about 19 times the payment allowance of J9201. At this time the newest gemcitabine product is not paid under HCPCS code J9201, and we believe that its assignment to a single source drug billing and payment code should be reevaluated.

Applying our proposal to all gemcitabine injection products, that is, the lyophilized powders, the concentrated injection and the newest diluted injection formulation, reveals that all products are gemcitabine injections, all products share the same labeled indications (treatment of ovarian, breast, non-small cell lung, and pancreatic cancers), product labeling is very similar (for example, the clinical studies referred to in the package insert appear to be the same, survival rates, adverse reaction rates, contraindications and warning sections of the labeling include virtually identical information), and based on dosage and administration, pharmacokinetics, indications and other sections of the product labeling, we expect these drug products to be used and prescribed in the same way. The result of the application of our proposal is that we would determine that the new gemcitabine product meets the definition of multiple source drug and assign it to the existing multiple source HCPCS code and the payment allowance for all the products in the code would be based on the volume-weighted average of the ASPs of all the NDCs of such products.

As discussed earlier in this comment response, we believe that this policy approach would not negatively affect innovation. We also believe that our approach could help prevent situations where any change to a product that distinguishes a 505(b)(2) drug product from a previous product approved under an ANDA, no matter how trivial (for the purpose of Medicare Part B drug payment), can result in very high prices and Part B payments for inexpensive, small molecule drugs that are similar to other inexpensive products in the market. Also, assigning section 505(b)(2) drug products to corresponding multiple source drug codes could encourage competition among products that are competitors—that is, when the products are described by one billing code and share similar labeling.

Comment: Several commenters expressed concerns about how grouping potentially expensive to acquire section 505(b)(2) drug products into multiple source drug codes may create situations where a provider's Medicare payment would be less than the acquisition cost and that this situation could lead to drugs not being available through some providers. One commenter pointed out that this could be more problematic for smaller practices.

Response: As discussed in a previous comment response, we believe that the application of our proposal would result in a limited number of section 505(b)(2) drug products being assigned to multiple source drug codes. Also, when products are assigned to HCPCS codes for payment under section 1847A of the Act, the products' sales volume and averages sales price may affect the weighted average ASP-based payment limit.

Since 2005, average sales price-based payment limits described in section 1847A of the Act have been determined using sales volume weighted averages. Each calendar quarter, a product's average sales price as reported by the manufacturer and the number of units sold by the manufacturer are included in the statutorily mandated payment calculation with other products that are assigned to a given HCPCS code. The ASP-based payment limit depends on the manufacturer reported volume of sales for a given product within a code and the reported ASP. Thus, as more units of a product are sold, that product's contribution to the weighted average increases.

We understand that in some cases a payment limit that is determined based on a weighted average can result in payment amounts that are below the acquisition costs of products that are sold at prices that are much higher than the ASP-based payment allowance. However, as noted previously, our policy would apply only to those section 505(b)(2) drug products that meet the definition of multiple source drug based at section 1847A(c)(6)(C), and manufacturers remain free to develop section 505(b)(2) drug products that would not meet the definition of multiple source drugs under our proposed approach, in which case such section 505(b)(2) drug products would not be assigned to multiple source billing and payment codes, and the concern about underpayment relative to acquisition cost would be mitigated. Also, in situations where a section 505(b)(2) drug product is assigned to a multiple source code, the section 505(b)(2) drug product can significantly influence payment limit calculations for a code if it competes successfully with similar products assigned to the multiples source drug code and achieves high sales volume (relative to the other products), particularly in situations where only a few low sales volume products are assigned to the code.

We also note that other factors can also influence acquisition cost. We do not have control over factors that can affect a provider's acquisition costs, for example, high launch prices set by manufacturers, sudden and unexpected price increases from manufacturers, markups from intermediaries such as wholesalers, lack of discounts (including volume discounts to smaller providers) and price differences for various classes of trade.

Comment: Several commenters expressed concern about the proposals' effects on patients. Most of these commenters focused on the effects on manufacturers, such as potential for less innovation by manufacturers leading to fewer drug approvals, fewer options for the treatment of patients, and impaired access. One commenter also requested that we consider the overall financial effects on patients, including effects on drug availability. This commenter expressed concerns about manufacturers' attempts to secure high payments for drugs and recognized CMS' concerns about manufacturers gaming the payment system in a manner that negatively affects consumers and results in diminished competition, but the commenter was also concerned about whether the policy may also have negative effects on patients.

Response: We have replied to concerns about the impact on manufacturers, innovation, providers and effects on access in general in previous comment responses. We do not believe that there is a strong justification for such concerns about access because of the limited scope of the proposals. That is, the proposals would result in limited number of section 505(b)(2) drug products being assigned to multiple source drug codes.

Much of our concern about negative effects on patients is related to increases in Part B drug spending that have been occurring for many years. From 2011 to 2016, Medicare FFS drug spending increased from $17.6 billion to $28 billion under Medicare Part B, representing a compound annual growth rate (CAGR) of 9.8 percent, with per capita spending increasing 54 percent, from $532 to $818. The number of Medicare Part B FFS beneficiaries and the number of these beneficiaries who received a Part B drug increased over the 5-year period (2011 through 2016). However the increase in total Medicare drug spending during this period is more fully explained by increases in the prices of drugs and mix of drugs for those beneficiaries who received them than by increases in Medicare enrollment and drug utilization. The CAGR in the number of Medicare Part B FFS beneficiaries is less than 1 percent between 2011 and 2016 (83 FR 54549 through 50).

We have concerns that if incentives to develop minimally modified products with high prices are not minimized, spending on such products will increase and contribute to increases in overall Part B drug spending. For individual patients, cost sharing amounts for section 505(b)(2) drug products, particularly for patients who do not have supplementary insurance, could increase as illustrated by the gemcitabine example discussed in a previous comment where there is a very substantial (approximately 19 times) difference between payments for a multiple source drug code and a corresponding product approved under the pathway established under section 505(b)(2) of the FFDCA. If similar situations become more common, such differences in payment amounts may contribute to increases in overall spending that in turn contribute to increases in Part B premiums that help fund Part B payments. Increases in Part B drug spending could also lead to increases in premiums for those with supplementary insurance.

Comment: A few commenters supported finalizing the proposals in order to curb drug prices and to pay similar amounts for similar services. The commenters agreed that products recently approved through the pathway established under section 505(b)(2) of the FFDCA were significantly more expensive than existing products and brought up the issue of ''evergreening'' (which includes actions such as securing patents or approvals for minimally modified versions of drugs to preserve high payments) and its effects on generic drug market by way of contribution to higher drug spending for products that do not improve outcome or quality. Not finalizing the proposal was characterized by a commenter as providing incentive for manufacturers to seek more section 505(b)(2) pathway approvals of higher priced products that are comparable to previously approved products. One commenter stated that the case by case determinations described in the proposed rule have been effective, have not sacrificed safety or access, and that continuing this approach would reduce opportunities for manufacturers to game FDA drug labeling in a manner that results in high, single source payments over extended periods of time for multiple source products.

Response: We agree with the commenters and the concern about the potential negative impact on innovation that could occur if all section 505(b)(2) drug products are paid as single source drugs under Part B. Permitting the payment of all section 505(b)(2) drug

products as single source drugs could continue to incentivize the development of minimally modified, high priced products, particularly injectable drug products used incident to a physician's services. This situation could shift manufacturers' focus from innovation to profit and thus contribute to high launch prices, high acquisition and inventory costs for providers, higher cost sharing and premiums in scenarios similar to the newer gemcitabine injection product approved through the section 505(b)(2) pathway that was discussed in an earlier comment response. This newer product shares dosing, pharmacokinetics, adverse effect profile, and indications on labeling with generic products but is packaged in a ready to administer IV bag, has a WAC (as reflected in pharmaceutical pricing compendia as of November 11, 2020) of $760 per 2 grams, about 19 times the payment allowance of the multiple source gemcitabine code, J9201.

Comment: One commenter stated that the proposal will not reduce high launch prices.

Response: We disagree. Although, the effect on launch prices is likely to be limited because we do not anticipate that many section 505(b)(2) drug products will be paid under multiple source codes, in situations where payment under a multiple source drug code occurs, we believe that manufacturers would not have an incentive to set high launch prices.

Comment: Several commenters expressed conditional or partial support for the proposal. This includes commenters who objected to finalizing the proposals for reasons discussed in previous comments but also stated that if CMS nevertheless finalized the proposals, CMS should provide more detail about the framework and the determination process and also should delay finalizing the proposal.

Commenters that suggested a delay in finalizing or implementing the proposals provided a variety of reasons for doing so. Some commenters requested CMS to provide more details about the process, including more specifics on how factors described in the proposal, for example differences in the active ingredient and labeling, might be interpreted and which drug products might be affected. Several commenters also requested that CMS provide more time for assessing the proposals so that the public could better understand them and provide an opportunity, such as through future rulemaking, for public input both on the proposals and on decisions about specific drug products. The current public health emergency (PHE) for COVID–19 was also mentioned by some commenters as an obstacle to engaging with CMS on this issue or responding fully to the proposal, and a reason for why a delay in finalizing the proposal is warranted. Other commenters who expressed concerns about rising drug prices supported the proposals on the condition the beneficiary access was not impaired and that the financial impact on patients is considered.

Response: We believe that we have proposed a clear process that includes a variety of factors such as drug names, labeling and indication to determine whether a section 505(b)(2) drug product meets the definition of multiple source drug at section 1847A(c)(6)(C) of the Act and thus should be assigned to an existing multiple source drug code. The proposals are also consistent with longstanding CMS drug payment policy.

However, we appreciate commenters' concerns about implementing the proposals and requests for additional time for further evaluation and engagement. It appears that some commenters may have misunderstood the limited scope of our proposal because they believe that many 505(b)(2) drug products would be affected. We understand that providing more detail with respect to our proposal may be helpful to a variety of stakeholders and that a better understanding of the policy will assist with planning and more efficient product procurement during a period where time and other resources may be scarce.

Comment: One commenter suggested that if finalized, the policy should be phased in, for example by changing the payment for a drug product by 25 percent increments over a 4-year time period to close the difference between a section 505(b)(2) drug product's current payment and the payment for the HCPCS code to which it would be assigned.

Response: We thank the commenter for this suggestion. However, we do not believe that there is authority under section 1847A of the Act to adjust payment allowances in the manner the commenter suggests.

Comment: Commenters also provided comments on the following issues: Payment to providers for the costs associated with the acquisition of a drug product; payments for the administration of section 505(b)(2) drug products; preferred coverage; formularies as well as the role of utilization management like step therapy and prior authorization for Part B drugs; the application of the process to biologicals; speeding up the coding process so that codes are available at product launch; payments for new technology; and the implementation of MedPAC recommendations.

Response: These comments are considered to be out of scope of the proposed rule, and therefore, we are not addressing in this final rule.

5. Decision

As discussed in the preceding responses to comments, we continue to believe that we have authority to assign certain section 505(b)(2) drug products to existing multiple source drug codes based on an interpretation of section 1847A of the Act and that our approach does not conflict with previously published program instruction or the FDA's therapeutic equivalency ratings.

However, in response to commenters requesting more detail about our proposed approach and requests to delay finalizing a decision, we are not finalizing the section 505(b)(2) drug product proposals or the proposed corresponding regulation text changes for 2021. The delay will also provide time for CMS to further consider this issue. We thank commenters for their responses.

M. Updates To Certified Electronic Health Record Technology Due to the ONC 21st Century Cures Act Final Rule

1. Background

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, enacted February 17, 2009) authorized incentive payments to eligible professionals, eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). In 2010, the Office of the National Coordinator for Health Information Technology (ONC) launched the Health IT Certification Program (ONC Health IT Certification Program) to provide for the certification of health IT. Requirements for certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary. The ONC Health IT Certification Program supports the use of certified health IT under the programs that we administer, including, but not limited to, the Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), the Quality Payment Program (QPP), and the Hospital Inpatient Quality Reporting (IQR) Program. While these programs continue to require the use of certified health IT, the use of certified health IT

has expanded to other government and non-government programs. The Promoting Interoperability Programs and QPP require the use of CEHRT as defined at 42 CFR 495.4 and 414.1305, respectively. Since 2019, in general, this has consisted of EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition. Similarly, the Hospital IQR Program began requiring that hospitals use only technology certified to the 2015 Edition certification criteria beginning with the CY 2019 reporting period/FY 2021 payment determination (83 FR 41607).

The ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (hereinafter referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961), finalized a number of updates to the 2015 Edition of health IT certification criteria (hereinafter referred to as the 2015 Edition Cures Update). We believe the 2015 Edition Cures Update will enhance interoperability and patients' access to their electronic health information, consistent with section 4006(a) of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). The ONC 21st Century Cures Act final rule revised, added new, and removed certification criteria that establish the capabilities and related standards and implementation specifications for the certification of health IT. In the CY 2021 PFS proposed rule (85 FR 50267), we proposed to require that technology used to meet the CEHRT definitions must be certified in accordance with the updated certification criteria in the ONC 21st Century Cures Act final rule.

The 2015 Edition Cures Update represents a limited set of changes relative to the overall set of health IT certification criteria currently required for the Promoting Interoperability Programs and QPP. These changes incorporate technical standards, including an e-prescribing standard required for alignment with other CMS programs, and other technical updates to existing 2015 Edition functionality used by many health care providers. For example, updates to 2015 Edition certification criteria referencing the United States Core Data for Interoperability (USCDI) standard, rather than the Common Clinical Data Set (CCDS) regulatory definition do not require extensive changes to user-facing aspects of health IT already certified to these criteria (85 FR 25665).

For CY 2019 and subsequent years, the CEHRT definitions for the Promoting Interoperability Programs at § 495.4, and for QPP at § 414.1305, require the use of EHR technology that is certified under the ONC Health IT Certification Program and meets the 2015 Edition Base EHR definition at § 170.102. In addition, the CEHRT definitions require the technology to be certified to certain other 2015 Edition health IT certification criteria, as specified in the definitions, including criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and criteria necessary to report on applicable objectives and measures specified under the MIPS Promoting Interoperability performance category (previously known as the Advancing Care Information performance category). The updates finalized by ONC in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) impact criteria in the different elements of the CEHRT definitions. This includes certification criteria included in the 2015 Edition Base EHR definition, as well as the additional certification criteria necessary to report on applicable objectives and measures to be a meaningful EHR user under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category.

The ONC 21st Century Cures Act final rule outlines a number of timelines and compliance dates for health IT developers related to the 2015 Edition Cures Update. The final rule finalized the removal of several certification criteria from the 2015 Edition that were included in the Base EHR definition, upon the effective date of the final rule (June 30, 2020). For other certification criteria, the final rule finalized a limited period during which ONC–Authorized Certification Bodies (ONC–ACBs) may continue to issue certificates for these criteria to health IT developers, after which certification will no longer be available.

Where the ONC 21st Century Cures Act final rule finalized updates to existing 2015 Edition certification criteria, or introduced new 2015 Edition certification criteria, ONC generally finalized that health IT developers have 24 months from the publication date of the final rule (until May 2, 2022) to make technology available that is certified to the updated, or new criteria. Subsequently, on April 21, 2020, in response to the PHE for COVID–19, ONC announced additional flexibility for health IT developers subject to the policies in the ONC 21st Century Cures Act final rule (*https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf*). Specifically, ONC announced that it would exercise enforcement discretion regarding new requirements in the ONC 21st Century Cures Act final rule, until 3 months after each initial compliance date or timeline (August 2, 2022).

In response to additional calls for increased flexibility in response to the PHE for COVID–19, ONC published an interim final rule with comment period at 85 FR 70064, on November 4, 2020 entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereinafter the ''ONC interim final rule''). In this rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to new or updated criteria available, ONC extended the timeline until December 31, 2022 (and until December 31, 2023 for § 170.315(b)(10), ''EHI export''). ONC stated that in order to reduce confusion, it has aligned these dates to the calendar year where they impact CMS program participants as aligning these compliance dates to the calendar year, also aligns them to the CMS program annual cycle. As noted in the CY 2021 PFS proposed rule, during this transition period, health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to implementing updates (85 FR 50266).

Below is an overview of the updates finalized in the ONC 21st Century Cures Act final rule that impact certification criteria included in the CEHRT definitions, as well as a discussion of associated timelines finalized in the ONC 21st Century Cures Act final rule, as revised in the ONC interim final rule.

The ONC 21st Century Cures Act final rule finalized removing the following criteria from the 2015 Edition certification criteria upon the effective date of the final rule (June 30, 2020), which included removing the following criteria from the 2015 Edition Base EHR definition (85 FR 25657 through 25660):

- ''Problem list'' at § 170.315(a)(6);
- ''medications'' at § 170.315(a)(7);
- ''medication allergies'' at § 170.315(a)(8); and

• ''smoking status'' at § 170.315(a)(11).

The ONC 21st Century Cures Act final rule noted that the functionality associated with these criteria is now widespread among health IT products, and is expected to remain in products absent certification. Accordingly, ONC sought to reduce burden associated with the certification program by removing these criteria (85 FR 25657 through 25660).

The ONC 21st Century Cures Act final rule also removed the ''data export'' criterion at § 170.315(b)(6) from the Base EHR definition, upon the effective date of the final rule (June 30, 2020) (85 FR 25668). However, this criterion will continue to be available for certification until December 31, 2023, as finalized in the ONC interim final rule (85 FR 70064). The ONC 21st Century Cures Act final rule instead established a new criterion, ''electronic health information export'' at § 170.315(b)(10), which requires a certified health IT module to electronically export all electronic health information (EHI), as defined in § 171.102, that can be stored at the time of certification by the product of which the health IT module is a part. A health IT developer of certified health IT products, which, at the time presented for certification electronically stores EHI, must certify such products to this new criterion and make these products available to their customers by December 31, 2023. However, the new EHI Export criterion is not included in the Base EHR definition (85 FR 25690), and it is not associated with any objectives or measures in the Promoting Interoperability Programs, or the MIPS Promoting Interoperability performance category.

In the ONC 21st Century Cures Act final rule, ONC finalized ''time-limited'' certification for several additional certification criteria associated with measures under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category from the 2015 Edition:

• ''Drug-formulary and preferred drug list checks'' at § 170.315(a)(10);

• ''secure messaging'' at § 170.315(e)(2); and

• ''patient-specific education resource'' at § 170.315(a)(13).

In order to allow participants in the Medicaid Promoting Interoperability Program to continue to have access to technology meeting 2015 Edition certification criteria to meet the measures for that program, ONC stated in the ONC 21st Century Cures Act final rule that ONC–ACBs may continue to issue certificates for these criteria until January 1, 2022 (85 FR 25660 through 25662).

Specifically, in the proposed rule we noted that the latter two criteria are necessary for participants to meet two of the measures in the Medicaid Promoting Interoperability Program. The ''secure messaging'' criterion at § 170.315(e)(2) is required to meet Objective 6 (Coordination of Care through Patient Engagement) and Measure 2 (Secure Messaging) (80 FR 62852). Similarly, the ''patient-specific education resource'' at § 170.315(a)(13) is necessary to fulfill the requirements of Objective 5 (Patient Electronic Access to Health Information) and Measure 2 (Patient-Specific Education) (80 FR 62846). We did not propose any changes to these measures in the CY 2021 PFS proposed rule (85 FR 50265 through 50272), as the final year of the Medicaid Promoting Interoperability Program is CY 2021. Based on the phased approach that ONC finalized, Medicaid eligible professionals may continue to use certified technology meeting those two criteria in CY 2021, which will enable them to report on these measures for the CY 2021 Medicaid Promoting Interoperability Program EHR reporting period. Health IT developers are encouraged to maintain the certified functionality for those two criteria through CY 2021, even if they move forward with updates to other criteria. Furthermore, the Secure Messaging measure is one of three measures within Objective 6, and eligible professionals need only meet two of the measures (§ 495.24(d)(6)(i)(B)). Even without the secure messaging functionality, an eligible professional could meet the other two measures and fulfill the objective. There is no similar option for the Patient-Specific Education measure, which is required to meet Objective 5.

The ''drug-formulary and preferred drug list checks'' criterion is also currently associated with measures under the Electronic Prescribing objective for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category (80 FR 62882 and 83 FR 59817). As discussed below, since ONC will retire this criterion after January 1, 2022, this criterion would no longer be required for e-Prescribing measures for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, beginning in CY 2021 (85 FR 25678).

The ONC 21st Century Cures Act final rule also finalized updates to a number of certification criteria, which are currently associated with objectives and measures under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, as well as criteria that are included in the 2015 Edition Base EHR definition. In general, ONC finalized that health IT developers have 24 months from the publication date of the final rule to make technology certified to these updated criteria available to their customers (until May 2, 2022). Subsequently, in the ONC interim final rule published on November 4, 2020, ONC further extended these compliance dates until December 31, 2022, in response to the PHE for COVID–19. During this time, developers are expected to continue supporting technology certified to the prior version of the 2015 Edition certification criteria for use by their customers.

The ONC 21st Century Cures Act final rule updated several criteria to include references to the USCDI standard, rather than the existing CCDS definition (85 FR 25670), and implemented related technical updates (85 FR 25671). These include the following criteria:

• ''Transitions of care'' at § 170.315(b)(1);

• ''clinical information reconciliation and incorporation'' at § 170.315(b)(2);

• ''view, download, and transmit to 3rd party'' at § 170.315(e)(1);

• ''transmission to public health agencies—electronic case reporting'' at § 170.315(f)(5); and

• ''application access—all data request'' at § 170.315(g)(9).

The USCDI standard establishes a set of data classes and constituent data elements required to support interoperability nationwide, designed to expand in an iterative and predictable way over time.[110] In finalizing version 1 of the USCDI, the ONC 21st Century Cures Act final rule added three new data classes, ''allergies and intolerances,'' ''clinical notes,'' and ''provenance;'' and added several additional elements to ''patient demographics'' that were not defined in the CCDS (85 FR 25912).

With respect to the use of secure, standards-based application programming interface (APIs), the ONC 21st Century Cures Act final rule finalized a new standards-based API criterion at § 170.315(g)(10), ''standardized API for patient and population services,'' which requires the use of FHIR Release 4 and several implementation specifications (85 FR 25742). Developers must make technology certified to this criterion available by December 31, 2022, as finalized in the ONC interim final rule

[110] For more information about the USCDI, see *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

(85 FR 70064). This criterion replaces the existing ''application access—data category request'' certification criterion at § 170.315(g)(8). However, ONC–ACBs may continue to issue certificates for § 170.315(g)(8) until December 31, 2022, permitting certification to either criterion during this transition period. The ONC 21st Century Cures Act final rule also added the new API criterion at § 170.315(g)(10) to the 2015 Edition Base EHR definition.

The ONC 21st Century Cures Act final rule also revised the ''electronic prescribing'' criterion at § 170.315(b)(3) to reference the NCPDP SCRIPT standard version 2017071 (85 FR 25678). As with the other updated criteria above, health IT developers have until December 31, 2022 to make technology certified to the updated criterion available to their customers, as finalized in the ONC interim final rule (85 FR 70064). However, we note that ONC has discontinued certification of new products to the former electronic prescribing criterion using the NCPDP SCRIPT standard version 10.6, in order to align with CMS requirements for use of the updated NCPDP SCRIPT standard under Part D, adopted as of January 1, 2020 (85 FR 25679). Products that were previously certified may maintain certification status until December 31, 2022 as developers are updating their products, and health care providers may continue to use these certified health IT modules for CMS program participation.

Finally, the ONC 21st Century Cures Act final rule updated the certification criterion for clinical quality measures ''Clinical Quality Measures (CQMs)—Report'' at § 170.315(c)(3), which is included in the CEHRT definitions (85 FR 25686). These updates remove the HL7 QRDA standard requirements from the criterion, and instead require support for the CMS QRDA Implementation Guides, upon the effective date of the final rule (June 30, 2020). In the ONC interim final rule, ONC issued a correction stating that health IT developers would have until December 31, 2022 to make technology available to their customers meeting the updated criterion.

For further discussion, we refer readers to the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961), and section III.M.3.b. of this final rule for discussion specific to the Hospital IQR Program.

As noted above, in general, health IT developers have until the date finalized in the ONC interim final rule, December 31, 2022, to make technology certified to the updated criteria available to their customers. As described in the proposed rule (85 FR 50268), after this date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified by ONC.

ONC expects and requires that developers will notify customers when technology certified to the updated criteria is available, and that developers will introduce these updates into certified health IT products in the manner most appropriate for their customers, such as through the course of normal maintenance (85 FR 25642). As discussed in the ONC 21st Century Cures Act final rule (85 FR 25666), health care providers may use the Certified Health IT Product List (CHPL) to identify the specific certification status of a product at any given time. The CHPL distinguishes certification to the existing 2015 Edition certification criteria from certification to the updated criteria adopted in the ONC 21st Century Cures Act final rule, by referring to the new and revised criteria as the 2015 Edition Cures Update, allowing health care providers to identify when a specific Health IT Module was updated. (*https://chpl.healthit.gov/*)

2. Updates to 2015 Edition Certified Electronic Health Record Technology Requirements in the Promoting Interoperability Programs and Quality Payment Program, Due to the ONC 21st Century Cures Act Final Rule

In consideration of the updates made to 2015 Edition certification criteria as described in the CY 2021 PFS proposed rule (85 FR 50265 through 50272), we proposed that the technology used by health care providers to satisfy the definitions of CEHRT at §§ 495.4 and 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We explained this includes technology used to meet the 2015 Edition Base EHR definition at § 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and technology certified to the criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, as specified in the CEHRT definitions.

As discussed above, the ONC 21st Century Cures Act final rule finalized compliance dates for health IT developers, and established which versions of certification criteria meet the certification requirements under the ONC Health IT Certification Program based on those compliance dates. In other words, the ONC 21st Century Cures Act final rule established timelines for (1) a transition period where technology certified to the prior or the updated versions of the same certification criteria would be considered certified, and (2) the date for which technology certified to only the updated version of the certification criteria would be considered certified. A health care provider must use technology certified under the ONC Health IT Certification Program to meet the CEHRT definitions. Therefore, we proposed that health care providers participating in the Promoting Interoperability Programs or QPP would be required to use only technology considered certified under the ONC Health IT Certification Program, according to the timelines finalized in the ONC 21st Century Cures Act final rule. For updated and new certification criteria included in the CEHRT definitions in §§ 495.4 and 414.1305, ONC finalized that health IT may be certified to the current 2015 Edition certification criteria or the 2015 Edition Cures Update criteria for a period of 24 months, as described in timelines finalized in the ONC 21st Century Cures Act final rule (85 FR 25670). ONC then announced an additional 3 months during which ONC stated it would exercise enforcement discretion in response to the PHE for COVID–19 and continue to allow health IT certified to either version of the criteria to be considered certified. We explained in the proposed rule that under our proposal, during that time period (up to 27 months from May 1, 2020, or until August 2, 2022), program participants would be able to use technology certified to either version, and that technology would be considered certified under the ONC Health IT Certification Program. Subsequently, in ONC's interim final rule, ONC extended the compliance dates for certification criteria finalized in the ONC 21st Century Cures Act final rule, finalizing that health IT may be certified to either the existing 2015 Edition certification criteria or the 2015 Edition Cures Update until December 31, 2022. As the ONC interim final rule extended compliance dates for the updated certification criteria until December 31, 2022, technology certified by ONC under the ONC Health IT Certification Program to the existing 2015 Edition certification criteria, or certified to the 2015 Edition and updated to the 2015 Edition Cures Update will now be considered certified by ONC under the

ONC Health IT Certification Program until December 31, 2022.

While the ONC 21st Century Cures Act final rule did not finalize a new Edition of certification criteria, this approach is similar to the prior policy for transition periods between Editions. For example, during the transition period in which the ONC Health IT Certification Program included both the 2014 Edition and the 2015 Edition, a health IT module certified to either Edition was considered certified, and technology certified to either Edition, or a combination of the two, could be used by health care providers to meet CEHRT definitions and demonstrate meaningful use (see 82 FR 38490 for a discussion of the CY 2018 transition between 2014 and 2015 Editions for eligible hospitals and CAHs). After the end of the transition period, only health IT certified to the 2015 Edition could be used by health care providers to meet the CEHRT definitions and demonstrate meaningful use, and health IT modules certified to only the 2014 Edition were no longer considered certified under the ONC Health IT Certification Program. In the same manner, after the current transition period ends, health care providers must use technology certified to only the updated version of the certification criteria finalized by ONC for the ONC Health IT Certification Program to meet the CEHRT definitions and demonstrate meaningful use.

Health care providers should refer to the Certification Criteria and Conditions and Maintenance of Certification requirements in 45 CFR part 170 for details about the updated certification criteria and timelines for health IT developers associated with the criteria. The ONC Health IT Certification Program regulations specify the requirements for what health IT developers must make available to customers and the associated timelines.

In previous rulemaking, to assist readers in identifying the requirements of CEHRT for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category objectives and measures, we provided tables identifying the 2015 Edition certification criteria required to meet those objectives and measures (see 83 FR 59817 for the MIPS Promoting Interoperability performance category). We noted two instances in which updates in the ONC 21st Century Cures Act final rule affect information we have provided in past rulemaking regarding the certification criteria that support specific Promoting Interoperability objectives and measures.

First, we noted that the ONC 21st Century Cures Act final rule is retiring the ''drug-formulary and preferred drug list checks'' criterion at § 170.315(a)(10), which is currently identified as supporting measures under the Electronic Prescribing objective (80 FR 62882 and 83 FR 59817). ONC finalized that this criterion requires certification until January 1, 2022, before being retired (85 FR 25667). We noted that removing this criterion from the Certification Program will have negligible impact on health care providers. As discussed in prior rulemaking, health care providers have noted that formulary checks are a promising approach. However, the utility of the specific functionality that is certified is not necessarily consistently applicable for all prescriptions (80 FR 62833). In addition, as it does not remove the product from the market, any health care providers who are using the current functionality may continue to use this technology for their own purposes. Accordingly, we noted that this certification criterion would no longer be associated with the measures under the Electronic Prescribing objective for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, beginning with the CY 2021 reporting and performance periods.

Second, we stated that under the new API certification criterion, ''standardized API for patient and population services'' at § 170.315(g)(10), which requires the use of FHIR Release 4, health IT developers have 24 months from the publication date of the ONC 21st Century Cures Act final rule to make technology available that is certified to this new criterion, which is part of the 2015 Edition Base EHR definition. We stated that after 24 months, ONC will retire the current ''application access—data category request'' at § 170.315(g)(8), which is currently identified as supporting the ''Provide Patients Electronic Access to Their Health Information'' measure (80 FR 62882 and 83 FR 59817). We stated that health IT meeting either criteria are considered certified during the 24-month period. Table 42, shows that either the existing criterion at § 170.315(g)(8), or the newly finalized criterion at § 170.315(g)(10), could be used by health care providers to complete the actions of the ''Provide Patients Electronic Access to Their Health Information'' measure for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category. Allowing health care providers the flexibility of using EHR technology that is certified to either criterion during this transition period would allow early adopters of the newly finalized criterion at § 170.315(g)(10), as well as those using technology meeting the existing certification criterion, to be able to meet the requirements of the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category. As discussed above, in the ONC interim final rule, ONC updated compliance dates finalized in the ONC 21st Century Cures Act final rule to extend the 24-month period described above to December 31, 2022.

In light of the changes described above with respect to the ''e-Prescribing'' and ''Provide Patients Electronic Access to Their Health Information'' measures we included Table 42 in the CY 2021 PFS proposed rule (85 FR 50270), shown below. Table 42 provided details on the measures for the Promoting Interoperability Programs for eligible hospitals and CAHs and the MIPS Promoting Interoperability performance category, and the certification criteria that support each measure. We also included in Table 42 the certification criteria that support the reporting of eCQMs. We noted that Table 42 is only applicable for the measures under the Promoting Interoperability Programs and for the Promoting Interoperability performance category of MIPS. Table 42 does not include all of the updated certification criteria included in the CEHRT definition as discussed in the CY 2021 PFS proposed rule (85 FR 50265 through 50272). Last, Table 42 has been updated to include the Health Information Exchange (HIE)(alternative) Bi-Directional Exchange measure, as this was finalized in section IV.A.3.c.(4)(c)(ii)(B) of this final rule, under the MIPS Promoting Interoperability performance category. For further discussion of changes to criteria under the CEHRT definition, we referred readers to the ONC 21st Century Cures Act final rule (85 FR 25667).

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TABLE 42: Medicare Promoting Interoperability Objectives and Measures, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)[3]	Health Information Exchange (HIE) Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria: § 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(4)[1] Transmission to cancer registries § 170.315(f)(6)[2] Transmission to public health agencies — antimicrobial use and resistance reporting § 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting[2]	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible professionals, and eligible hospitals and CAHs	§ 170.315(c)(1) § 170.315(c)(2) § 170.315(c)(3)(i) and (ii) § 170.315(c)(4) [4] (optional)

[1] = Specific to Eligible Clinicians (MIPS Promoting Interoperability performance category)
[2] = Specific to Eligible Hospitals and CAHs (Promoting Interoperability Programs)
[3] = Specific to Eligible Clinicians, finalized in section IV.A.3.c.(4)(c)(ii)(B) of this final rule (MIPS Promoting Interoperability performance category)
[4] = In the CY 2021 PFS proposed rule, (c)(4) was inadvertently listed as (c)(3); correction noted here

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In the CY 2021 PFS proposed rule, we proposed to revise two definitions under § 414.1305 (85 FR 50270). First, under the definitions of CEHRT, we proposed to replace the reference to the ''Advancing Care Information'' performance category with the ''Promoting Interoperability'' performance category, to reflect the performance category name change that we made previously (83 FR 59785). Second, under the definition of Meaningful EHR user for MIPS, we proposed to replace the reference to the ''Advancing Care Information'' performance category with the ''Promoting Interoperability''

performance category, to reflect the performance category name change that we made previously (83 FR 59785).

We sought public comments on all of these proposals.

Comment: Many commenters supported CMS' proposal that the technology used by health care providers to satisfy the definitions of CEHRT must be certified under the ONC Health IT Certification Program in accordance with the updated 2015 Edition certification criteria, as finalized in the ONC 21st Century Cures Act final rule. Commenters indicated the update would harmonize requirements, create more efficiencies, and facilitate true interoperability between EHRs. Commenters were also in favor of eliminating inconsistencies and reducing costs by having the ability to use technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition Cures Update, or a combination of the two. One commenter observed that the alignment with the ONC 21st Century Cures Act final rule would reduce provider confusion.

Response: We agree that this proposal will reduce confusion for health care providers, continue with our efforts to promote interoperability, and reduce burden by streamlining efforts across programs, and components of the Department.

Comment: Several commenters expressed appreciation that, during the transition period, health care providers will have the flexibility to meet the CEHRT definition using technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition Cures Update, or a combination of the two. Further, commenters stated that this alignment would reduce administrative burden, eliminate redundancies, streamline objectives and measures, ensure health care providers are using up-to-date technology, and encourage continued efforts to align reporting requirements across care settings.

Response: We agree that health care providers participating in the Promoting Interoperability Programs and QPP will have flexibility during this transition period to use EHR technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition and updated to the 2015 Edition Cures Update, or a combination of EHR technologies. We also agree with commenters that this alignment will reduce administrative burden, and support our efforts to achieve alignment across programs, care settings, and components of the Department.

Comment: Several commenters stated that the August 2, 2022 compliance date discussed in the CY 2021 PFS proposed rule occurs in the middle of a program year and would create additional challenges and complexity for planning. Commenters also expressed concern that the proposed mid-year requirement would limit reporting flexibility for providers participating in the Hospital IQR Program, the Advanced-APM track within QPP, and those opting to use eCQMs under MIPS. These commenters requested guidance regarding the relationship between the deadline and annual reporting requirements.

Response: We appreciate commenters' concerns that the August 2, 2022 compliance date discussed in the CY 2021 PFS proposed rule may introduce additional complexity for stakeholders who manage technology upgrades and program reporting based on the calendar year.

As noted above, the ONC interim final rule has extended the compliance dates for health IT developers associated with the updated certification criteria finalized in the ONC 21st Century Cures Act final rule. Specifically, ONC has extended compliance dates that originally fell 24-months after the publication of the ONC 21st Century Cures Act final rule, to December 31, 2022. This means that technology meeting the existing 2015 Edition criteria will be considered certified under the ONC Health IT Certification Program through the end of 2022.

With the extension of the compliance dates in the ONC interim final rule, we believe it is appropriate to align the transition period during which health care providers participating in the Promoting Interoperability Programs or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the extended compliance date of December 31, 2022. We believe that this extension of the transition period to include all of 2022 will address commenter concerns regarding the complexities associated with a mid-year transition date. We are therefore finalizing a modification to our proposal, and extending the transition period to the new December 31, 2022 compliance date as finalized in the ONC interim final rule. After this date, only certified technology updated to the 2015 Edition Cures Update will be considered certified and may be used by health care providers to meet the definitions of CEHRT for the Promoting Interoperability Programs and QPP.

However, we reiterate that health care providers would not be required to demonstrate that they are using updated technology to meet the CEHRT definitions immediately upon the transition date of December 31, 2022. In accordance with the reporting and performance period requirements of the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, participants are only required to use technology meeting the CEHRT definitions during a self-selected reporting or performance period of a minimum of any consecutive 90 days in CY 2022 (85 FR 58966 through 58967 and section IV.A.3.c.(4)(b) of this final rule, respectively). For instance, under this final policy, a health care provider could demonstrate meaningful use for any consecutive 90-days during CY 2022 using either technology certified to the existing 2015 Edition, or certified technology that has been updated to the 2015 Edition Cures Update, or a combination of non-updated and updated certified health IT modules to meet the CEHRT definition. Under the MIPS Promoting Interoperability performance category, as described in section IV.A.3.c.(4)(b) of this final rule, a MIPS eligible clinician could then choose a performance period of any consecutive 90 days to demonstrate meaningful use during 2023, up to the final 90 days of 2023. The MIPS eligible clinician would not be required to demonstrate meaningful use of technology meeting the 2015 Edition Cures Update until the 90-day performance period they have selected. Moreover, we remind readers that a MIPS eligible clinician is not required to report on possession of certified technology for the 90-day performance period they have selected, but instead, they are required to report on how many times they used certified technology for the completion of the action defined by each measure. Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

With regard to alignment with other CMS programs that also require or reference the use of certified EHR technology, we expect to collaborate with these programs in the future to ensure alignment across CMS programs, and that the timelines for implementation discussed in this final rule are not adversely impacted by other CMS program requirements.

Comment: Many commenters did not support our proposal to require the use of technology certified to the 2015 Edition Cures Update, due to concerns with health IT vendors. Specifically, commenters are concerned with vendors

being able to complete, and providers being able to adopt and implement, the changes associated with the 2015 Edition Cures Update by August 2, 2022, when only updated technology would be considered certified under the ONC Health IT Certification Program.

Commenters specifically expressed concern that in aligning deadlines between health care providers and vendors, there would not be sufficient time for health care providers to adopt and implement the newly available technology. Some commenters requested additional time beyond the vendor deadline to select and implement certified health IT, test the new technology, customize the new technology for their specific practices, update workflows, and train staff.

A few commenters expressed concern that complications associated with transitioning between versions of certified technology could negatively affect patient care, and lead to potential patient harm. Several commenters urged CMS to extend the transition period for using technology certified to either the current 2015 Edition or the 2015 Edition Cures Update for CMS reporting and incentive-based programs. As alternatives, commenters recommended January 2023, August 2023, January 2024, and August 2024 as potential deadlines.

Response: We appreciate commenters' concerns related to the effort required for health care providers to adopt and implement updated technology to meet the CEHRT definition, after it is made available by health IT developers. However, we disagree that our proposal would not permit adequate time for implementing and using the 2015 Edition Cures Update in a manner similar to what commenters are requesting.

Under our proposed rule, we stated that a health care provider must use technology that is considered certified under the ONC Health IT Certification Program to meet the CEHRT definitions, in accordance with updates to the 2015 Edition of health IT certification criteria, as finalized in the ONC 21st Century Cures Act final rule. In our proposed rule, we stated that this proposal would allow health care providers to use either technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition Cures Update, or a combination of the two, prior to the date established by ONC, regardless of the health care provider choosing to update their certified technology in a phased-in approach, or at one time. Specifically, we stated that during CY 2022, a health care provider implementing updates in a phased approach could plan to use a combination of updated and non-updated certified health IT for any consecutive 90-day reporting or performance period prior to August 2, 2022, and then complete their first reporting or performance period using only updated health IT modules in CY 2023. Similarly, we stated that if a health care provider was planning to update all of their certified technology at one time in order to engage in a more extensive testing and implementation period during CY 2022, they could complete their 90-day reporting or performance period for CY 2022, prior to August 2, 2022 using non-updated health IT, and then complete their first reporting or performance period using only updated health IT modules in CY 2023 (85 FR 50268).

Under the revised compliance dates finalized in the ONC interim final rule, both technology certified to the existing 2015 Edition and technology certified to the 2015 Edition Cures Update would now be considered certified until December 31, 2022. As noted above, we are finalizing that health care providers may use health IT certified to the existing 2015 Edition certification criteria, certified health IT updated to the 2015 Edition Cures Update, or a combination of updated and not-yet updated health IT modules, for the full year in CY 2022. For a reporting or performance period *after* December 31, 2022, health care providers would need to use only technology certified to the 2015 Edition Cures update to meet the CEHRT definitions.

We believe the additional flexibility finalized in the ONC interim final rule as well as the performance period flexibilities permitted under the MIPS Promoting Interoperability performance category, as described in section IV.A.3.c.(4)(b) of this final rule, will allow sufficient time for health IT developers to make updated products available for health care providers to demonstrate meaningful use. This timeframe would allow developers and MIPS eligible clinicians as much as 3 years and 5 months (or, 41 months total) from the publication of ONC's 21st Century Cures Act final rule, before a MIPS eligible clinician seeking to demonstrate meaningful use would be required to use technology meeting the 2015 Edition Cures Update for their 90-day performance period in CY 2023 under the Promoting Interoperability performance category. We believe this is a sufficient amount of time for MIPS eligible clinicians to implement and use updated technology after it is made available by health IT developers. Historically, commenters have requested a total of 36 months from the publication of a new Edition of health IT certification criteria to the time it is required for use by health care providers participating in CMS programs. As discussed in the proposed rule, updates to the certification criteria that ONC finalized in the ONC 21st Century Cures Act final rule do not constitute a full new Edition of technology (85 FR 25665), as the scope of updates did not warrant implementation of an entirely new Edition of certification criteria (85 FR 25664 through 25665). Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

The updates finalized in the ONC 21st Century Cures Act final rule are limited in scope to build on existing functionality and standards in technology certified to the 2015 Edition, which participants in CMS programs have been using as part of clinical and administrative workflows since the 2019 program year. Specifically, as described in the ONC 21st Century Cures Act final rule (85 FR 25665), updates to the technology that require additional technical development by health IT developers, and which impact participants in CMS programs, include: (1) Updating eCQM and e-prescribing criteria to align with existing CMS requirements; (2) modifying existing interoperability criteria to reference the USCDI standard; and (3) updating certification of the API functionality for patient access. For eCQMs, the updates required in the ONC 21st Century Cures Act final rule bring the criterion in line with the updates already required for CMS quality programs, which are implemented on an annual basis. For the e-prescribing criterion, the updates required in the ONC 21st Century Cures Act final rule bring the criterion in line with the requirements for the Medicare Part D program, which required use of an updated e-prescribing standard beginning on January 1, 2020 (84 FR 23832). For the USCDI updates, ONC noted that the updates to the common clinical data set (CCDS) to create the USCDI were intentionally limited to a modest expansion that most health IT developers already supported, were already working toward, or should be capable of updating their health IT to support in a timely manner (85 FR 25665). Additionally, while there may be some development burden on health IT developers to update current criteria from the CCDS to the USCDI, there would be limited burden on health care

providers to send or receive additional data types or to provide additional data points to patients using the same health IT capabilities that currently support these workflows. Similarly, since 2019, health care providers with systems certified to 2015 Edition certification criteria that participate in the Promoting Interoperability programs or the Promoting Interoperability performance category in MIPS have implemented workflows for patients to access their information using API technologies certified to the 2015 Edition for the purposes of reporting for the ''Provide Patients Electronic Access to their Health Information'' measure. The update to the FHIR-based API should not be a significant change to these workflows for the provider, as these changes are technical modifications within the system rather than significant changes to clinical or administrative workflows.

Therefore, while implementation and testing of updates in the 2015 Edition Cures Update will be necessary, the updates to the eCQM and e-prescribing criteria are already being implemented under existing CMS programs. In addition, we believe the updates for the USCDI and API will be largely seamless for health care providers and will not require substantial redesign of existing clinical and administrative workflows for health IT users. Instead, the majority of the burden associated with these updates falls on health IT developers of certified health IT, as discussed in the regulatory impact analysis in the ONC 21st Century Cures Act final rule (85 FR 25912).

Regarding recommendations from commenters that we establish separate deadlines for health care providers to use technology meeting the 2015 Edition Cures Update, we do not believe that such timelines would be consistent with the level of burden described above or with HHS priorities to advance interoperability in a timely fashion. For instance, if we adopted the recommendation to not require health care providers to use updated technology until 2024, as recommended by some commenters, this could mean that a health care provider would not implement and use certified technology updated to the 2015 Edition Cures Update until 4 years after the publication of updated criteria in the ONC 21st Century Cures Act final rule. Therefore, the benefits of technology updates such as FHIR-based API capabilities, which can be implemented today, would not be available to patients for over 4 years from their inclusion in the ONC Health IT Certification Program. We do not believe that such a lengthy delay in improving patient access to their health information would be consistent with our priorities for the Promoting Interoperability Programs or QPP.

We also wish to emphasize that, under the ONC 21st Century Cures Act final rule, health IT developers may make technology meeting updated criteria available to health care providers at any time prior to the compliance dates finalized in the ONC interim final rule, and may begin to support health care providers in implementing these updates. Our policy would allow health care providers to use either technology certified to the current 2015 Edition, technology certified to the 2015 Edition and updated to 2015 Edition Cures Update, or a combination of the two, to meet the CEHRT definitions beginning with the 2020 reporting and performance periods upon the effective date of this final rule.

We declined to set an independent additional deadline for health care providers participating in the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category to use updated technology, as we believe that existing flexibility around when health care providers must demonstrate meaningful use during the calendar year will provide sufficient time for health care providers to implement and use updated certified technology. Moreover, we believe that any further extension of timeframes beyond what we have discussed in this final rule would result in unacceptable delays in making important technology updates available, which HHS has determined are critical for improving interoperability across the nation in a timely fashion and improving the quality of care for patients.

Comment: Several commenters expressed concern that updated 2015 Edition certified health IT would be cost prohibitive, and recommended that CMS allow additional time for health care providers to implement these updates, so that they would have an opportunity to recover from the financial effects of the PHE for COVID–19 before being required to implement technology meeting the 2015 Edition Cures Update. A few commenters stated that aligning deadlines between CMS and ONC could lead to significant financial burdens in an already compromised environment. Commenters expressed concern with vendors making excessive charges to clients to guarantee meeting required deadlines, or, vendors deciding not to issue an updated product thereby reducing market competition, and potentially further increasing the cost for available products. Several commenters stated that the costs to cover such expansive EHR upgrades were not approved in this fiscal years' budget, leaving little room for unexpected high costs.

Response: We appreciate commenters' concerns regarding the financial impact of the PHE for COVID–19 on health care providers. We proposed that participants in the Promoting Interoperability Programs and QPP be required to use technology considered certified under the ONC Health IT Certification Program to meet the CEHRT definitions, consistent with the timelines finalized in the ONC 21st Century Cures Act final rule. As discussed above, the ONC interim final rule published in the November 4, 2020 **Federal Register** provided additional flexibility by extending compliance dates for updated certification criteria finalized in the ONC 21st Century Cures Act final rule to December 31, 2022. To align with this change, we are finalizing our proposal with a modified timeframe, as discussed in our previous responses to comments. We believe this extended timeframe will offer health care providers additional flexibility to manage the financial impacts of the PHE for COVID–19 with respect to when they implement and begin using technology updated to the 2015 Edition Cures Update.

Regarding pass through and development costs, we would like to reiterate a few points as discussed above. First, with the extended timeline, health care providers have the ability to use technology certified to the existing 2015 Edition certification criteria or updated to the 2015 Edition Cures Update to demonstrate meaningful use, starting from the effective date of this final rule. Moreover, in many cases, we believe these updates will be implemented by health IT developers as part of routine cyclical updates, such as the annual updates to CMS eCQMs. We believe the ability to implement these changes through routine service and maintenance updates will reduce the pressure on health care providers to meet an expedited timeline. Second, as discussed above, the required updates are based on existing capabilities that vendors have already deployed as part of the 2015 Edition, reducing the likelihood that developers will not pursue updates to their products. For health care providers who have concerns regarding their respective vendor, we again want to encourage the use of CHPL. As discussed above, the CHPL distinguishes certification to the existing 2015 Edition certification criteria from certification to the updated

criteria adopted in the ONC 21st Century Cures Act final rule, by referring to the new and revised criteria as the 2015 Edition Cures Update, allowing health care providers to identify when a specific health IT module was updated. (*https://chpl.healthit.gov/*) Last, to understand the impact on health IT developers associated with updating health IT products, we refer readers to the impact analysis presented in the ONC 21st Century Cures Act final rule at 85 FR 25912.

Comment: A few commenters were supportive of our proposals, but asked that CMS and ONC continue to monitor the PHE for COVID–19, and adjust compliance deadlines as appropriate. A few concerns commenters shared surrounding the PHE for COVID–19 included administrative burdens for health care providers, potential risks to patients and their safety, and the financial burden for those already struggling financially and administratively amidst the PHE for COVID–19. As an alternative, commenters suggested implementing two separate timelines, allowing additional time to recoup financial costs and recover from the PHE for COVID–19. The first timeline being for developers to make updated 2015 Edition products available as finalized under the ONC 21st Century Cures Act final rule, immediately followed by a second timeline specifically for health care providers to adopt and implement these updated products.

Response: We appreciate the concerns raised by commenters, but respectfully disagree. As mentioned above, our alignment with the additional flexibility finalized in the ONC interim final rule, coupled with the existing flexibilities permitted under the MIPS performance period requirements for the Promoting Interoperability performance category described in section IV.A.3.c.(4)(b) of this final rule, allows developers and MIPS eligible clinicians as much as 3 years and 5 months from the publication of ONC's 21st Century Cures Act final rule before they must use certified technology updated to the 2015 Edition Cures Update. Given the limited scope of the updates and the importance of supporting patient access and care coordination, we believe a single aligned timeline for developers to make updates available and for subsequent provider implementation and use is appropriate. Health care providers have the option to use either technology certified to the existing 2015 Edition, or certified technology that has been updated to the 2015 Edition Cures Update, or a combination of non-updated and updated certified health IT modules through December 31, 2022, with the ability to choose a phased-in, or one time approach to implementing these updates. Additionally, as discussed above, MIPS eligible clinicians are only required to use technology meeting the CEHRT definition during any self-selected performance period of a minimum of any consecutive 90-days, including the last 90-days of 2023, for the Promoting Interoperability performance category in CY 2023 (see section IV.A.3.c.(4)(b) of this final rule). Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

Regarding recommendations that we establish two separate implementation deadlines (one for health IT developers, and one for health care providers), we do not believe that such timelines would be consistent with the level of burden previously discussed, with HHS priorities to advance interoperability in a timely fashion, or our efforts to maintain alignment across programs and components of the Department. We further believe that a single timeline for health care provider use of updated technologies that is aligned to the compliance timelines for health IT developers allows for the most efficient transition for health care providers in planning and executing implementation of updates in preparation for a reporting period in CY 2023.

Comment: One commenter supported the alignment between CMS and ONC, but shared concerns with the ability of all health care providers to meet the proposed deadlines. The commenter instead suggested that early adopters be rewarded with bonus points and/or counting this as an improvement activity.

Response: We will take these suggestions under consideration for future rulemaking.

Comment: Several commenters urged CMS to work with ONC to ensure that health care providers are not held accountable for delays in implementation or adoption caused by the health IT vendors. One commenter said that health care providers cannot control vendor compliance, and urged CMS to work with ONC to ensure that health care providers are not harmed, either by being penalized for vendor non-compliance or through high pass-through costs.

Response: We remind commenters that under the Promoting Interoperability Programs for eligible hospitals and CAHs, CMS may grant, on a case-by-case basis, hardship exceptions for extreme and uncontrollable circumstances, which may include vendor issues or issues related to decertified EHR technology. Information on the hardship exception request process is available on the CMS Promoting Interoperability web page at *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship*. Eligible clinicians participating in the MIPS Promoting Interoperability performance category may submit a hardship exception request through the QPP website at *https://qpp.cms.gov/login*. For more information on the hardship exception process under MIPS, please also refer to *https://qpp.cms.gov/mips/exception-applications*.

Comment: Some commenters were not supportive of CMS' proposal to require updates to 2015 Edition certified health IT in accordance with the timeline set forth in the ONC 21st Century Cures Act final rule to meet the CEHRT definitions. Commenters expressed concern with, and lack of confidence in, any presumption that technology updated in accordance with the 2015 Edition Cures Update will facilitate seamless interoperability, as these updates encompass a significant development effort. Commenters encouraged CMS to consider alternative means to the proposed timelines.

Commenters urged CMS to work in concert with federal partners that are working to address the same issues now to ensure its approach aligns with theirs, and to minimize compliance burdens on affected stakeholders. One commenter recommended that CMS engage clinicians in developing the requirements for future updates to certification criteria for health IT referenced by the CEHRT definitions.

Response: We respectfully disagree with commenters that the updates to certification criteria finalized in the ONC 21st Century Cures Act final rule will not help to improve interoperability for health care providers and patients. As discussed in the CY 2021 PFS proposed rule, the updates to 2015 Edition certification criteria are primarily focused on incorporating standards that are broadly supported across industry as important steps to improve interoperability. For instance, the USCDI version 1, which is referenced in several updated certification criteria, adds clinical notes and provenance as data elements to the existing CCDS based on significant feedback from the industry. Both the free text portion of the clinical notes

and the provenance of data have been identified by clinicians as data that is important *to clinicians* but is often missing during electronic health information exchange.

Similarly, we believe implementation and use of technology certified to the new certification criterion for a standards-based API in the 2015 Edition Cures Update will help to create an environment that promotes innovation for software developers to connect new tools and services that create efficiencies for health care providers throughout their course of care delivery. By enabling access to data through the new, standards-based API, clinicians will have increased access to applications that can help support use cases for population health analytics, clinical decision support, patient education, as well as to conduct administrative and financial tasks. For further information, we refer readers to the discussion of the benefits associated with increased interoperability enabled by APIs in the ONC 21st Century Cures Act final rule (85 FR 25922).

In response to commenters who expressed concerns that this alignment will not result in a seamless transition, we respectfully disagree and note that this approach avoids potential negative consequences of misalignment. As an example, not aligning the requirements for the use of certified technology under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category with the updated 2015 Edition certification criteria finalized in the ONC 21st Century Cures Act final rule could lead to increased stakeholder confusion on how to meet individual program requirements, gaps in availability of essential functionality and standards, and lack of adoption of updated technology that supports patient safety and quality outcomes. This would increase burden by requiring health care providers to maintain the same health IT, but applied differently to two different program areas.

In response to commenters requesting that CMS continue to work alongside Federal partners to ensure that we approach overlapping issues similarly, we agree. CMS and ONC will continue to work together keeping HHS' priorities to advance interoperability in a timely fashion as a priority. The theme of alignment is also integral across program areas, across components of the Department, and across the care-continuum. We will continue to work together, and continue to highlight these areas of alignment for health care providers.

For commenters recommending that CMS engage clinicians in developing the requirements for future updates to CEHRT, we appreciate this suggestion. Health care providers are welcome to submit suggestions via the Promoting Interoperability Call for Measures, for eligible hospitals and CAHs, or eligible clinicians. Health care providers are also encouraged to submit comments and suggestions in responses to proposed rules including the annual IPPS and PFS proposed rules. We also encourage health care providers to listen to, participate in, and submit questions or comments through Promoting Interoperability webinars for hospitals and CAHs, and eligible clinicians.

Comment: Several commenters supported revising the two definitions referencing the ''Advancing Care Information'' performance category, and changing this to read the ''Promoting Interoperability'' performance category under § 414.1305.

Response: We would like to thank commenters for their support.

Comment: One commenter recommended that CMS remove the 45 CFR 170.315(c)(2) and (3) criteria from the CEHRT definition for MIPS and QPP, to allow more eligible clinicians to participate in A–APMs and other-Payer A–APMs that use CQM collection types without leveraging eCQM functionality. It was suggested that CMS and ONC make the CQM criteria optional for those who choose to use the eCQM collection type. The commenter stated this would allow additional eligible clinician types to use certified criteria as appropriate for their respective fields, without needing to possess and maintain technology that is not necessary.

Response: We thank commenters for their input, and note that the CEHRT definitions already provide this type of flexibility for health care providers to obtain and implement only those criteria that they need to use based on specific program measures and submission methods. The CEHRT definitions do require the 45 CFR 170.315(c)(1) criterion, which is a part of the 2015 Edition Base EHR definition. However, implementation and use of both the 45 CFR 170.315(c)(2) criterion and the 45 CFR 170.315(c)(3) criterion is contingent upon what is necessary to report on applicable objectives and measures. These two criteria are required if the health care provider is reporting eCQMs directly from their EHR for their program participation. However, the criteria are not required if they are not required by the specific CQM reporting option that the health care provider chooses.

After consideration of the public comments received, we are finalizing our proposals with a modification to align the transition period during which health care providers participating in the Promoting Interoperability Programs or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December 31, 2022 date established in the ONC interim final rule for health IT developers to make updated certified health IT available.

This will allow health care providers to use either not yet-updated technology certified to the existing 2015 Edition, or certified technology that has been updated to the 2015 Edition Cures Update, or a combination of non-updated and updated certified health IT modules, starting from the effective date of this final rule through the end of CY 2022. Health care providers would then be required to use only certified technology updated to the 2015 Edition Cures Update for a performance period in CY 2023. As discussed in our responses to comments, we note that, consistent with the MIPS Promoting Interoperability performance category performance period described in section IV.A.3.c.(4)(b) of this final rule, a MIPS eligible clinician is not required to demonstrate use of updated technology beginning on January 1, 2023. Rather, a MIPS eligible clinician participating in the Promoting Interoperability performance category may select a performance period of any consecutive 90-days as late as the last 90-days in 2023 to meet the CEHRT definitions using technology meeting the 2015 Edition Cures Update. Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

3. Changes to Certification Requirements Under the Hospital IQR Program Due to the 21st Century Cures Act Final Rule

a. Background and Previously Finalized Certification Requirements

To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the

statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509) for the measures we have previously adopted for the Hospital IQR Program measure set for the FY 2022 payment determination and subsequent years. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

The Hospital IQR Program strives to put patients first by empowering patients to make decisions about their own healthcare along with their clinicians using information from data driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across HHS, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves. The Hospital IQR Program measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care.

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period. Hospital IQR Program file format requirements have progressed over time to support quality reporting based on data submitted from EHRs that use relevant, up-to-date, standards-based structured data capture. We updated our requirements with the adoption of health IT certified to new Editions of certification criteria referenced in the CEHRT definition, originally requiring hospitals submitting eCQM data to use technology certified to the 2014 Edition certification criteria (79 FR 50252) and evolving to the current requirement that hospitals use technology certified to the 2015 Edition certification criteria for reporting eCQMs and hybrid measures (83 FR 41604 through 41607, and 84 FR 42507). In order to ease the transition between Editions of certified health IT, the Hospital IQR Program offered flexibility in file submission requirements, allowing the use of either the 2014 Edition or the 2015 Edition for multiple reporting periods (80 FR 49705 through 49708; 81 FR 57169 through 57170; 82 FR 38397 through 38391). As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57111), our goal is to align electronic quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, as much as feasible so that the reporting burden on healthcare providers will be reduced (82 FR 38392). In the past we noted that aligning the eCQM submission requirements of the Hospital IQR Program and the Promoting Interoperability Programs reduces burden for hospitals as they may report once and fulfill the requirements of both programs (84 FR 42599). We intend to continue to align the eCQM reporting requirements for the Hospital IQR Program and Promoting Interoperability Programs to reduce reporting burden (84 FR 42598 through 42601; 82 FR 38479).

b. Revisions to the Existing Certification Requirements

Recently, through the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) published on May 1, 2020, ONC updated the 2015 Edition of health IT certification criteria (''2015 Edition Cures Update''). Specifically, the ONC 21st Century Cures Act final rule finalized updates to existing 2015 Edition certification criteria and introduced new 2015 Edition criteria. As noted in section III.M.1. of this final rule, in general, the ONC 21st Century Cures Act final rule provided that health IT developers have up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers. During this period, health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to updating their products (85 FR 25642 through 25961).

In April 2020, ONC announced its intention to exercise enforcement discretion as to the compliance dates finalized in the ONC 21st Century Cures Act final rule in response to the PHE for COVID–19.[111] As a result, where the ONC 21st Century Cures Act final rule required health IT developers to make technology meeting new and updated certification criteria available by May 2, 2022, ONC stated developers taking advantage of enforcement discretion would be permitted to delay making updated certified technology available until 3 months after each initial compliance date or timeline.

Given the Hospital IQR Program's history of updating file submission requirements, we understand that transitioning to technology certified to a new Edition, or to an updated version of the same Edition of certification criteria, can be complex. Nevertheless, we believe that there are many benefits to using relevant, up-to-date, standards-based structured data capture with an EHR to support electronic clinical quality measurement. In addition, we believe it is important to continue to align with the eCQM reporting requirements for the Promoting Interoperability Programs (82 FR 38479, 84 FR 42598).

Therefore, in the CY 2021 PFS proposed rule (85 FR 50270 through 50272), for the Hospital IQR Program beginning with the CY 2020 reporting period/FY 2022 payment determination[112] and for subsequent years, we proposed to expand flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41537 through 41608), or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961). We are clarifying in this final rule that this proposed flexibility applies to all Hospital IQR Program measures which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures. We also refer readers to sections III.M.1. and III.M.2. of this final rule for background and more details about the 2015 Edition Cures Update. We proposed to adopt this flexible approach in order to encourage hospitals to implement the most up-to-date, standards-based structured data capture while also maintaining alignment with the Promoting Interoperability Program proposal. We noted that the proposal would allow hospitals that are early adopters of certified health IT that has

[111] *https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf.*

[112] We note that the CY 2021 PFS proposed rule stated that this proposal would begin with CY 2020 reporting period/FY 2023 payment determination (85 FR 50271). We are clarifying that this proposal will begin with the CY 2020 reporting period, which corresponds with the FY 2022 payment determination.

been updated to the 2015 Edition Cures Update to implement those changes while still meeting Hospital IQR Program requirements. We also noted that we will revisit this topic in future rulemaking as for further alignment with the ONC 21st Century Cures Act final rule. We sought public comment on our proposal.

We noted that, among other changes and of particular relevance to hospitals that participate in the Hospital IQR Program, the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at § 170.315(c)(3) to refer to CMS QRDA Implementation Guides and removes the Health Level 7 (HL7®) QRDA standard requirements (85 FR 25645). Under the Hospital IQR Program, we previously encouraged health IT developers to test any updates on an annual basis, including any updates to the eCQMs and eCQM reporting requirements for the Hospital IQR Program, based on the CMS QRDA I Implementation Guide for Hospital Quality Reporting (CMS Implementation Guide for QRDA) (82 FR 38393). The CMS Implementation Guide for QRDA, program specific performance calculation guidance, and eCQM electronic specifications and guidance documents are available on the eCQI Resource Center website at *https://ecqi.healthit.gov/*. To be clear, the ONC 21st Century Cures Act final rule removes the HL7® QRDA standards from the relevant health IT certification criteria, which now refers directly to the CMS Implementation Guides for QRDA standards bringing their requirements into closer alignment with what we encourage under the Hospital IQR Program. Based on our data, the majority of Hospital IQR Program participants already use the CMS QRDA I Implementation Guide for Hospital Quality Reporting for submission of eCQMs to the Hospital IQR Program. We noted that we believe this update results in health IT developers no longer needing to maintain certification to the Health Level 7 (HL7®) QRDA base standards in addition to using the CMS QRDA I Implementation Guide for the Hospital IQR Reporting.

Since publication of the CY 2021 PFS proposed rule, in response to additional calls for increased flexibility in response to the PHE for COVID–19, on November 4th, 2020 ONC issued an interim final rule with comment entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereafter, ''ONC interim final rule'') (85 FR 70066). In the ONC interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to updated criteria available to their customers, ONC extended the timeline until December 31, 2022 (85 FR 70064). After that date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal to expand flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition as was previously finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41537 through 41608); or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) for the CY 2020 reporting period/FY 2022 payment determination and for subsequent years. A few commenters expressed their support and noted that CMS should consider the timeline for fully implementing the technology upgrades associated with the 2015 Edition Cures Update when considering requirements for future program years. One commenter noted their support for the required use of the CMS QRDA I Implementation Guide that will occur as a result of using the 2015 Edition Cures Update because it reduces burden on EHR developers.

Response: We agree that the standardization to use the QRDA I Implementation Guide will help in burden reduction for EHR developers. We will consider the timeline for fully implementing the technology upgrades associated with the 2015 Edition Cures Update when determining requirements for future program years. As noted above, in this final rule we are finalizing the proposed flexibility, which applies to all Hospital IQR Program measures, which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures.

Comment: A few commenters did not support our proposal due to concerns with the timeline and effort for health IT developers to certify and for providers to adopt the changes associated with the 2015 Edition Cures Update. These commenters specifically expressed concern that aligning the deadline for providers to adopt technology certified to the 2015 Edition Cures Update with the deadline for vendors to have this Edition available would not provide sufficient time for providers to adopt the newly available version. Some commenters noted that they require additional time beyond the vendor deadline to select and implement certified health IT, test the new technology, customize the health IT for their specific practices, and update workflows and train staff. The commenters urged CMS to extend the flexibility for using both technology certified to the current 2015 Edition and certified technology updated consistent with the 2015 Edition Cures Update as acceptable versions to be used for CMS reporting and incentive-based programs through CY 2023 or later.

Response: We emphasize that the proposal to allow hospitals to use either technology certified to the 2015 Edition or certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2020 reporting period/FY 2022 payment determination allows for greater flexibility. We want to avoid penalizing providers participating in the Hospital IQR Program who wish to adopt the updated technology earlier than the mandated deadline for the ONC Health IT Certification Program finalized by ONC by ensuring the providers who adopt early are still in compliance with Hospital IQR Program data submission requirements. We clarify that, for the Hospital IQR Program, beginning with the CY 2020 reporting period/FY 2022 payment determination, using certified technology updated to the 2015 Edition Cures Update is an acceptable option, but so is use of technology certified to the 2015 Edition certification criteria. For those that cannot use certified technology updated to the 2015 Edition Cures Update, technology certified to the 2015 Edition continues to be acceptable.

We understand commenters' concerns related to the effort it will take for providers to customize their health IT for their specific practices and to potentially update workflows and train staff when adopting updated certified technology once it is made available by health IT developers; however, we expect the burden of updating these criteria for providers to be no greater than that already required to comply with CMS annual updates. We recommend readers review section III.M.2. of this final rule, and the ONC 21st Century Cures Act final rule (85 FR 25667) for greater understanding of the scope of these updates and how this scope was considered in establishing the timelines for developer update.

Furthermore, as noted above, since publication of the CY 2021 PFS proposed rule, in response to additional calls for increased flexibility in response to the PHE for COVID–19, on November 4, 2020 ONC issued an interim final rule with comment entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereafter, ''ONC interim final rule'') (85 FR 70066). In the ONC interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to updated criteria available to their customers, ONC extended the timeline until December 31, 2022 (85 FR 70064).

Comment: One commenter noted that hospital and delivery systems are experiencing disruptions due to the PHE for COVID–19, which makes digital updates difficult during this time.

Response: We reiterate that our policy is intended to expand flexibility and avoid penalizing providers participating in the Hospital IQR Program who wish to adopt the updated technology earlier than the mandated deadline finalized by ONC by ensuring the providers who adopt early are still in compliance with Hospital IQR Program data submission requirements. We will accept data using either technology certified to the 2015 Edition criteria or certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY2020 reporting period/FY 2022 payment determination.

In addition, if a hospital experiences an extraordinary circumstance that prevents it from reporting eCQMs they are able to submit an individual extraordinary circumstances exception (ECE) request under the Hospital IQR Program. Specifically, in the FY 2016 IPPS/LTCH PPS final rule, we finalized a policy, effective starting with the FY 2018 payment determination, to allow hospitals to utilize the existing ECE form (OMB control number 0938–1022 (expiration date December 31, 2022)) to request an exception to the Hospital IQR Program's eCQM reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting (80 FR 49695, 49713). We stated that such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification (80 FR 49695, 49713)). We assess a hospital's request on an individual basis to determine if an exception is merited (80 FR 49695, 49713). We also refer stakeholders to additional eCQM ECE resources on QualityNet.[113] We also note that, in response to the PHE for COVID–19, ONC announced additional flexibility for health IT developers. Specifically, in the ONC interim final rule, ONC further extended the deadline for health IT developers to make technology certified to the updated criteria available to their customers until December, 31, 2022 (85 FR 70064).

Comment: A few commenters noted that the August 2, 2022 deadline for making technology meeting new and updated certification criteria available occurs in the middle of a program year, and therefore, limits flexibility for providers, including those participating in the Hospital IQR Program. These commenters requested guidance regarding the relationship between the deadline and annual reporting requirements for various programs including the Hospital IQR Program.

Response: In the proposed rule we discussed ONC's compliance date of August 2, 2022 for health IT developers to make updated certified health IT products available to their customers.[114] However, as mentioned above, since publication of the CY 2021 PFS proposed rule, ONC issued an interim final rule, which extended the date for health IT developers to make technology certified to the updated criteria available to their customers until December 31st, 2022 (85 FR 70064). For the CY 2022 reporting period/FY 2024 payment determination, hospitals must report the required number of quarters of eCQM data from the January 1, 2021 to December 31, 2022 reporting period, by 2 months following the close of the calendar year. (85 FR 58940). We refer readers to QualityNet.org for more information related to important dates and deadlines for the Hospital IQR Program.[115] We believe the change finalized in the ONC interim final rule, which aligns the compliance date for updating certified health IT under the ONC Health IT Certification Program with the calendar year, addresses the commenters' concern regarding misalignment with the annual reporting requirements for the Hospital IQR program.

After consideration of the public comments, we are finalizing our proposal as proposed.

N. Establishing New Code Categories

1. Background

Currently, there are four existing Level II HCPCS codes for buprenorphine/naloxone products (J0572–J0575), which describe groupings of products by different strengths as indicated on their FDA labels. When many payers assign a single payment rate to a single code, they typically do so under the expectation that the products can be substituted for one another in most clinical scenarios. As discussed in the CY 2021 PFS proposed rule (85 FR 50272), we have received feedback from stakeholders that there is variability in bioequivalence between the products within the range of strengths listed in each code descriptor, meaning that products within a current code are not necessarily substitutes for one another. Therefore, to facilitate more accurate coding and more specific reporting of the variety of buprenorphine/naloxone products on the market, we proposed an expanded series of codes to identify buprenorphine/naloxone products.

Specifically, we proposed to establish 15 new code categories for use to report all currently marketed buprenorphine/naloxone products, based on strength as well as therapeutic equivalence reflected in Table 43.

[113] See *https://www.qualitynet.org/inpatient/measures/ecqm/participation#tab2.*

[114] *https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf.*

[115] QualityNet.org, Hospital IQR Program Participation. Available at *https://www.qualitynet.org/inpatient/iqr/participation.*

TABLE 43: Proposed New Code Categories

HCPCS	Description
JXXX1	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 2mg; 0.5mg
JXXX2	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 4mg; 1mg
JXXX3	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 8mg; 2mg
JXXX4	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 12mg; 3mg
JXXX5	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 2.1mg; 0.3mg (Bunavail)
JXXX6	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 4.2mg; 0.7mg (Bunavail)
JXXX7	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 6.3mg; 1.0mg (Bunavail)
JXXX8	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual 2mg; 0.5mg
JXXX9	Buprenorphine Hydrochloride; Naloxone Hydrochloride; tablet; sublingual 8mg; 2mg
JXX10	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 0.7mg; 0.18mg (Zubsolv)
JXX11	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 1.4mg; 0.36mg (Zubsolv)
JXX12	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 2.9mg; 0.71mg (Zubsolv)
JXX13	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 5.7mg; 1.4mg (Zubsolv)
JXX14	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 8.6mg; 2.1mg (Zubsolv)
JXX15	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 11.4mg; 2.9mg (Zubsolv)

As the existing 4 codes would be replaced with more specific codes in the new code series, we also proposed to discontinue the existing codes in Table 44.

TABLE 44: Codes CMS Proposed to Discontinue

HCPCS	Description
J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine
J0575	Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine

The new code series would permit physicians and clinics to accurately bill insurers for the drug and dose utilized. For example, state Medicaid agencies would be able to more easily identify the drug dispensed, which would facilitate more efficient and accurate rebate invoicing for the Medicaid Drug Rebate Program. The expanded code series would also facilitate more specific and meaningful tracking of utilization of buprenorphine/naloxone products within and across their respective health insurance programs. We noted that these coding proposals would not change Medicare coverage or payment policies for oral or sublingual buprenorphine codes. The drug products described by these codes are not separately payable under Medicare Part B.

We received the following comments on the proposal to establish new code categories.

Comment: Several commenters supported our proposal to establish new code categories.

Response: We appreciate the comments in support of establishing the new code categories.

Comment: A few commenters suggested retaining the existing four codes and recommended that we not establish new code categories, on the basis that the proposed, expanded list of codes may result in confusion and additional work on the part of providers.

Response: We appreciate the comment in support of retaining the existing code categories and not establishing new code categories. As discussed below, in order to further consider the effects of an expanded code series, we have decided not to finalize our proposals at this time.

As a result of our review of the comments, some in favor of more granular coding and some in favor of less granular coding, we would like to further consider the appropriate level of coding granularity for buprenorphine/naloxone products. Thus, we have decided not to finalize our proposal to establish the 15 new code categories set forth in Table 43 or our proposal to discontinue the existing four HCPCS

codes (J0572, J0573, J0574 and J0575) listed in Table 44 at this time. The existing four codes in Table 44 will remain in effect on January 1, 2021.

O. Medicare Diabetes Prevention Program (MDPP)

In the CY 2021 PFS proposed rule (85 FR 50074), we proposed to amend our regulation at § 410.79(e) to describe the policies that will apply during certain emergencies (Emergency Policy). In addition, we proposed to amend § 424.210 to modify the definition of ''beneficiary engagement period'' and to address beneficiary engagement incentives that are furnished to MDPP beneficiaries who are receiving MDPP services virtually pursuant to the Emergency Policy.

1. Revisions to § 410.79(b)

We proposed to amend the Medicare Diabetes Prevention Program (MDPP) expanded model to revise certain MDPP policies adopted in the March 31st COVID–19 IFC (85 FR 19230) that would apply during the remainder of the PHE for COVID–19 and/or any future emergency period, and in an emergency area, as such terms are defined in section 1135(g) of the Act, where the Secretary has authorized section 1135 waivers for such emergency area and period (hereinafter referred to as an ''1135 waiver event'') where such 1135 waiver event may cause a disruption to in-person MDPP services (hereinafter referred to as an ''applicable 1135 waiver event''). We proposed that we would determine that an 1135 waiver event could disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include avoiding the transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries or MDPP coaches during an 1135 waiver event. We proposed that if we determine that an 1135 waiver event may disrupt in-person MDPP services, we would notify all impacted MDPP suppliers via email and other means as appropriate. Such notice would include the effective date when flexibilities described in § 410.79(e) would be available. We proposed that the applicable 1135 waiver event would end on the earlier of the end of the emergency period (as defined in section 1135(g) of the Act) or the date we determine that the 1135 waiver event no longer disrupts in-person MDPP services under the proposed standard described above.

We temporarily amended the MDPP expanded model to revise certain MDPP policies in the March 31st COVID–19 IFC. These changes apply only during the PHE for COVID–19. The March 31st COVID–19 IFC permits certain beneficiaries to obtain the set of MDPP services more than once per lifetime, waives the 5 percent weight loss eligibility requirements, and allows certain MDPP suppliers to either suspend the delivery of services or deliver virtual MDPP sessions on a temporary basis. We believe that establishing an Emergency Policy that applies more broadly will improve the current flexibilities for the remainder of the PHE for COVID–19 and provide MDPP suppliers and MDPP beneficiaries with flexibilities to address any future applicable 1135 waiver events.

The changes proposed in the CY 2021 PFS proposed rule would preserve the March 31st COVID–19 IFC MDPP flexibilities and apply them to future section 1135 waiver events, provide for additional flexibilities that would apply during the PHE for COVID–19 and future 1135 waiver events, clarify certain policies adopted in the IFC, and prospectively end a flexibility that would become unnecessary in light of our other proposals. We stated that the proposed flexibilities, if finalized, would supersede the flexibilities adopted in the March 31st COVID–19 IFC for the PHE for COVID–19. Thus, the proposed changes would be available for the remainder of the PHE for COVID–19 and for all future applicable 1135 waiver events, effective January 1, 2021.

We proposed these changes to address MDPP supplier and MDPP beneficiary needs in response to the PHE for COVID–19 and any future 1135 waiver events that result in an interruption to expanded model services delivered by MDPP suppliers and preventing MDPP beneficiaries from attending in-person sessions. Throughout the original rulemaking for the MDPP expanded model, we sought to ensure that the set of MDPP services would be delivered in-person, in a classroom-based setting, within an established timeline. During that rulemaking, CMS prioritized establishing a structured service that, when delivered within the confines of the rule, would create the least risk of fraud and abuse, increase the likelihood of success for beneficiaries, and maintain the integrity of the data collected for evaluation purposes. Based on lessons learned during the PHE for COVID–19, we proposed to allow temporary flexibilities that prioritize availability and continuity of services for MDPP suppliers and beneficiaries affected by extreme and uncontrollable circumstances that CMS determines may disrupt in-person MDPP services during an applicable 1135 waiver event using the standard articulated above. The overall intent of the proposed Emergency Policy is to minimize disruption of services for MDPP suppliers and beneficiaries.

The proposed flexibilities would be applicable to MDPP beneficiaries and MDPP suppliers (as such terms are defined in § 410.79(b)) as described herein. Our Emergency Policy does not permit an MDPP supplier to furnish MDPP services virtually during the PHE for COVID–19 or an applicable 1135 waiver event unless the MDPP supplier's preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) recognition authorizes the supplier to furnish services in-person. The MDPP supplier requirements at § 424.205 set forth parameters for suppliers to enroll in Medicare, including having any preliminary recognition established by the CDC for the purposes of the DPRP or full CDC DPRP recognition. The DPRP refers to a program administered by the CDC that recognizes organizations that are able to furnish the National Diabetes Prevention Program (National DPP) services, follows a CDC-approved curriculum, and meets CDC's performance standards and reporting requirements. The CDC assigns to each DPRP-recognized supplier an organizational code that specifies the service delivery mode (for example, in-person, online, distance learning, or combination). Because MDPP services are covered under Medicare only when they are furnished at least in part in-person, a supplier that does not have an organizational code authorizing in-person services (''virtual-only suppliers'') may not provide MDPP services, either virtually or in-person. We do not believe it is appropriate to permit virtual-only suppliers to furnish MDPP services when the proposed Emergency Policy is in effect. This is because MDPP suppliers must remain prepared to resume delivery of MDPP services in-person to start new cohorts and to serve beneficiaries who wish to return to in-person services when the proposed Emergency Policy is no longer in effect. Given the difficulty of predicting when the PHE for COVID–19 or any applicable 1135 waiver event will end, virtual-only suppliers may not have sufficient time to obtain the CDC's authorization to furnish in-person

services. Permitting virtual-only suppliers to furnish MDPP services during the PHE for COVID–19 or an applicable 1135 waiver event could disrupt the provision of services to MDPP beneficiaries when services resume on an in-person basis. Virtual only suppliers are not permitted to provide the set of MDPP services because MDPP beneficiaries may elect to return to in-person services after the PHE for COVID–19 or other applicable 1135 waiver event ends, and MDPP suppliers need to be able to accommodate their request. In addition, we are still requiring the MDPP suppliers to resume furnishing in-person the set of MDPP services after the applicable 1135 waiver event.

We proposed to amend the MDPP regulations to provide for certain changes, including allowing MDPP suppliers to start new cohorts during the remainder of the PHE for COVID–19 or a future applicable 1135 waiver event and allowing MDPP suppliers to either deliver MDPP services virtually, or suspend in-person services and resume services at a later date during an applicable 1135 waiver event. The proposed changes would permit certain MDPP beneficiaries to obtain the set of MDPP services more than once per lifetime, for the limited purposes of allowing a suspension in service due to an applicable 1135 waiver event and to provide the flexibilities that will allow MDPP beneficiaries to maintain eligibility for MDPP services despite a break in attendance.

In the March 31st COVID–19 IFC, we stated that we would allow MDPP suppliers to either deliver MDPP services virtually or suspend in-person services and resume services at a later date. In addition, we also provided in the March 31st COVID–19 IFC that the once per lifetime requirement waiver is only applicable to MDPP beneficiaries whose sessions were suspended or cancelled due to the PHE for COVID–19 (that is, MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020). However, we do not believe it is necessary to permit all MDPP beneficiaries to restart the set of MDPP services in all applicable 1135 waiver events. Therefore, we proposed that MDPP beneficiaries who elect to receive MDPP services virtually in accordance with the MDPP Emergency Policy are not eligible to restart the set of MDPP services at a later date. As proposed, the policy would ensure that MDPP beneficiaries who continue to receive the set of MDPP services virtually during an applicable 1135 waiver event cannot repeat the set of MDPP services at a later date, in accordance with the general once per lifetime limitation for the set of MDPP services established in § 410.79(c)(1)(i)(B).

We proposed the following approach for permitting MDPP beneficiaries to resume or restart the set of MDPP services in the event in-person sessions are suspended, and the MDPP beneficiary does not elect to receive MDPP services virtually. MDPP beneficiaries who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event would be eligible to restart the set of MDPP services at the beginning, or resume with the most recent attendance session of record, after the applicable 1135 waiver event has ended. Beneficiaries who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event would be eligible to restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or would be permitted to resume with the most recent attendance session of record. MDPP beneficiaries who are in the second year of the set of MDPP services would not be allowed to restart the set of MDPP services at the beginning.

We noted that we do not believe allowing MDPP beneficiaries who are already in the ongoing maintenance phase of MDPP to restart from the beginning aligns with the performance-based payment strategy upon which the expanded model relies to achieve savings. MDPP suppliers with beneficiaries who have successfully completed over half of the set of MDPP services have already benefited from the bulk of the permitted total performance-based payments. Allowing MDPP beneficiaries in the ongoing maintenance interval phase to restart the expanded model would result in an MDPP supplier being reimbursed for close to double the intended payment amount. Not only might this have a negative impact on the long term expanded model savings, this could result in beneficiaries being unfairly coerced into electing to start over instead of resuming the set of MDPP services where they left off. The proposal would apply prospectively only. Under the current MDPP regulations, as amended in the March 31st COVID–19 IFC, we waived the once per lifetime requirement for MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020 and whose sessions were suspended or canceled due to the PHE for COVID–19 to obtain the set of MDPP services more than once per lifetime by electing to restart the set of MDPP services or resume with the most recent attendance session of record. We proposed to retain that flexibility for those MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020 (and as discussed in greater detail below, are modifying this flexibility to apply to MDPP beneficiaries who were receiving the set of MDPP services as of March 31, 2020). Finally, we proposed that beneficiaries who elect to suspend the set of MDPP services at the start of an applicable 1135 waiver event and subsequently choose to restart the MDPP set of services at the beginning or to resume with the most recent attendance session of record, may only make such an election once per applicable 1135 waiver event. The proposed policy was intended to ensure that MDPP beneficiaries may not suspend and re-start the MDPP set of services multiple times during the same applicable 1135 waiver event, which would be contrary to the overall goal of the MDPP Emergency Policy, and to the goals of the MDPP expanded model as a whole.

We proposed that the limit placed on the number of virtual make-up sessions described at § 410.79 would not apply during the remainder of the PHE for COVID–19 or during any future applicable 1135 waiver event, so long as the virtual services are furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, follow the CDC-approved National DPP curriculum requirements, and the supplier has an in-person DPRP organizational code.

We proposed to amend the regulations to clarify that all sessions, including the first core session, may be offered virtually, not as ''virtual make-up sessions,'' but as a virtual class consistent with the in-person class curriculum, during the remainder of the PHE for COVID–19 and any future applicable 1135 waiver event. The MDPP supplier could still only furnish a maximum of one session on the same day as a regularly scheduled session and a maximum of one virtual make-up session per week to the MDPP beneficiary. We proposed that virtual sessions may be furnished to achieve both attendance goals and achieve weight-loss goals in the event that a qualifying weight measurement was obtained by one of the methods described herein. We proposed that an MDPP supplier may offer to an MDPP beneficiary: 16 virtual sessions offered weekly during the core session period; 6 virtual sessions offered monthly during the core maintenance session interval periods; and 12 virtual sessions offered monthly during the ongoing

maintenance session interval periods. MDPP suppliers may only furnish a maximum of one regularly scheduled session virtually and a maximum of one virtual make-up session per week to an MDPP beneficiary. As proposed, the number of allowable virtual core sessions would increase from 15 to 16. This change is due to the added proposed flexibility to allow MDPP suppliers to obtain weight measurements remotely (as described below) and to deliver the first core session virtually.

Under these temporary flexibilities, we proposed that the requirement for in-person attendance at the first core-session would not apply. We proposed that during the remainder of the PHE for COVID–19 and any future applicable 1135 waiver events, MDPP suppliers may obtain weight measurements from MDPP beneficiaries through the following methods: (1) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations; (2) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission (commonly referred to as ''Bluetooth™ enabled''); or (3) self-reported weight measurements from a participant's own at-home digital scale. We proposed that self-reported weights must be submitted via video, by the MDPP beneficiary to the MDPP supplier. The video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session. Due to this additional flexibility, we proposed that the waiver of the minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in § 410.79(e)(3)(iv) of the March 31st COVID–19 IFC (85 FR 19230) be ended. Thus, effective January 1, 2021, all MDPP beneficiaries would be required to achieve and maintain the required 5 percent weight loss goal in order to be eligible for the ongoing maintenance sessions, even if the PHE for COVID–19 remains in place as of that date.

We proposed to amend § 410.79(e). We sought comment on these proposals. We received public comments on the proposed changes to § 410.79(b). The following is a summary of the comments we received and our responses.

Comment: Several commenters requested clarification regarding whether beneficiaries are required to use digital scales to collect their body weights at home. Commenters expressed concern that some participants in MDPP would be unable to document their weight because they do not have either digital scales or smart phones to capture a photograph or video of their weight on a digital scale. For example, several commenters indicated that requiring beneficiaries to capture their weights via a digital scale by video, and then sending the video in a HIPAA-compliant manner to their MDPP supplier, may prove too burdensome for patients and create additional barriers to MDPP participation. Furthermore, commenters stated that MDPP beneficiaries may have limited access or ability to use the technology required to meet this method of reporting. These commenters contended that if beneficiaries are unable to present in-person for their MDPP sessions or secure digital transmissions of their weights, this could limit them from meeting the eligibility requirements to participate. Several commenters requested that we consider other options of self-reporting such as allowing patients to take their weight at home on the date of the MDPP session and report via a telehealth visit, via a phone call to the MDPP supplier, or securely communicate the weight measurement thru the Electronic Health Record secure messaging portal.

Response: We agree with the commenters that some beneficiaries may lack access to scales and phones with photograph or video capabilities. We proposed additional methods by which MDPP suppliers may obtain weight measurements from beneficiaries and allowing MDPP suppliers to obtain weight measurement from MDPP beneficiaries either in-person or via the use of technology, such as a Bluetooth-enabled scale or self-reported weight measurements using the MDPP beneficiary's digital scale and video technology.

After considering these comments, we are modifying the proposed § 410.79(e)(3)(iii)(C) to allow MDPP suppliers to accept self-reported MDPP beneficiary weight measurements via a photograph of their digital scale. In addition, § 424.210 allows MDPP suppliers to furnish MDPP beneficiaries with certain engagement incentives, including technological tools such as Bluetooth-enabled scales that support the goals of the expanded model and satisfy other conditions. We believe these options allow for MDPP beneficiaries with varying resources and comfort with technology to have their weight measured, and to participate in virtual MDPP services, in most circumstances. We also note that virtual participation in MDPP during an applicable 1135 event is voluntary. Beneficiaries may suspend and restart the set of MDPP services at a later date consistent with the policies we are adopting in this rule.

Comment: Multiple commenters urged CMS to add the MDPP set of services to the Medicare telehealth list, either temporarily during the PHE for COVID–19 or permanently. Commenters stated that access to telehealth services is critical beyond the PHE for COVID–19, as it helps address barriers such as program delivery in rural areas and transportation issues. Commenters stated that research shows that Medicare beneficiaries with prediabetes are at high risk for many chronic and comorbid conditions, including COVID–19. These commenters stated that many beneficiaries will not participate in in-person prediabetes prevention programs during the PHE due to social distancing rules or stay-at-home directives. The commenters noted that access for Medicare beneficiaries to telehealth MDPP services are essential during this PHE for access to MDPP services that can increase and maintain healthy lifestyles to prevent diabetes and comorbidities.

Similarly, other commenters urged CMS to increase access to virtual MDPP generally, or to make the flexibilities finalized in the March 31st COVID–19 IFC or in this rule applicable to circumstances outside of the PHE for COVID–19 or an applicable 1135 waiver event. One commenter states that, given the length of the current public health emergency, it is likely that additional data on satisfaction and efficacy of virtual DPP options will soon be available. Another commenter urged CMS to undertake a renewed actuarial analysis of virtual MDPP. This commenter also encouraged CMS to permit Medicare Advantage (MA) plans to use virtual MDPP encounters, in addition to in-person MDPP encounters, and to permit virtual DPP programs to register as Medicare suppliers in order to meet network adequacy requirements and satisfy the requirement to provide MDPP services.

Response: We appreciate the interest in adding the set of MDPP services to the Medicare telehealth list and allowing access to virtual MDPP outside the PHE for COVID–19 or other applicable 1135 waiver event. Inclusion of MDPP services on the Medicare telehealth list is not appropriate because virtual MDPP services do not qualify as telehealth services. The provisions we are finalizing in this rule are intended to ensure that beneficiaries participating in the set of MDPP services during the PHE for COVID–19 or any future applicable 1135 waiver event can maintain consistent access to care via virtual delivery of services with

minimal disruption throughout their entire set of MDPP services. The MDPP expanded model was actuarially certified for primarily in-person delivery. We are not allowing additional virtual delivery of the set of MDPP services beyond the Emergency Policy described in this final rule. We continue to explore options for making virtual MDPP services more widely available.

Comment: In general, commenters agreed that the final rule should permit MDPP beneficiaries to continue to participate in MDPP virtually during applicable 1135 waiver events. Other commenters indicated that beneficiaries should have a choice between receiving MDPP services virtually and waiting for in-person sessions to resume. In addition, beneficiaries who initially elect to receive MDPP services virtually, but later determine that virtual services do not work for them (for example, due to technological challenges, if the MDPP supplier is unable to offer a high quality program virtually, or if virtual services are not an effective tool for the beneficiary), or unforeseeable circumstances occur that do not allow them to continue or be successful virtually, they should have the option to suspend services at that time and resume in-person sessions at a later date.

Response: We agree with the suggestions made in this comment and are modifying our policy regarding the election of virtual services and its impact on the once-per-lifetime benefit for those beneficiaries receiving the MDPP set of services on or after January 1, 2021 during an applicable 1135 event or PHE. The final rule includes modifications that support the provision of virtual MDPP services and permit new cohorts to start. We are modifying our policy in this rule to allow MDPP beneficiaries participating in the set of MDPP services during the PHE for COVID–19 or any future applicable 1135 waiver event to continue receiving the set of MDPP services virtually even after the PHE for COVID–19 or other applicable 1135 waiver event ends. Please note that MDPP beneficiaries who opt to continue to receive the set of MDPP services virtually during an applicable 1135 waiver event cannot repeat the set of MDPP services at a later date, in accordance with the general once per lifetime limitation for the set of MDPP services established in § 410.79(c)(1)(i)(B). However, MDPP beneficiaries may decide to suspend virtual MDPP services and later resume the set of in-person MDPP services with the most recent attendance session of record once in-person services are available.

In addition, this rule allows certain beneficiaries to restart the set of MDPP services at the beginning. MDPP beneficiaries who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event are eligible to restart the set of MDPP services at the beginning, or resume with the most recent attendance session of record, after the applicable 1135 waiver event has ended. MDPP beneficiaries who are in the second year of the set of MDPP services as of the start of the applicable 1135 waiver event, are only permitted to restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or resume the set of MDPP services at the most recent attendance session of record. MDPP beneficiaries who are in the second year of the set of MDPP services are not allowed to restart the set of MDPP services at the beginning.

In the March 31st COVID–19 IFC, we waived the once per lifetime requirement for MDPP beneficiaries who were receiving the set of MDPP services as of March 1st, 2020 (changed in this rule to March 31st, 2020) and whose sessions were suspended or canceled due to the PHE for COVID–19. These MDPP beneficiaries may obtain the set of MDPP services more than once per lifetime by electing to restart the set of MDPP services. Alternatively, these MDPP beneficiaries can resume with the most recent attendance session of record, in which case they would not be eligible to restart thereafter. Finally, MDPP beneficiaries who suspend the set of MDPP services at the start of an applicable 1135 waiver event (or after virtual services have started) and subsequently choose to restart the MDPP set of services (to the extent they are eligible to do so) or resume with the most recent attendance session of record, may only make such an election once per applicable 1135 waiver event. Table B–N 45 summarizes the beneficiary options during an applicable 1135 waiver event.

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TABLE 45: Summary of MDPP Beneficiary Options during an Applicable 1135 Waiver Event

Beneficiary MDPP Status	Supplier Response to 1135 Waiver Event	During 1135 Waiver Event	1135 Waiver event ends and in-person services resume
Beneficiary is in first 12 months of MDPP set of Services when 1135 waiver event begins	Supplier Suspends MDPP set of services during 1135 waiver event	N/A	**Option 1**: Beneficiary may restart MDPP set of services at the first core session OR **Option 2**: Beneficiary may resume the set of MDPP services with the most recent attendance session of record
Beneficiary is in first 12 months of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to switch to the virtual MDPP set of services . Once virtual services have started, the beneficiary may suspend MDPP services at any time.	**Option 1**: Beneficiary may continue receiving services virtually until the conclusion of their services OR **Option 2**: Beneficiary may resume the set of in-person services with the most recent attendance session of record. If beneficiary received any part of the MDPP set of services virtually during an applicable 1135 waiver event, s/he cannot restart the set of MDPP services.
Beneficiary is in first 12 months of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to suspend in-person MDPP set of services and does not switch to the virtual MDPP set of services.	**Option 1**: Beneficiary may restart in-person MDPP set of services at the first core session OR **Option 2**: Beneficiary may resume the set of in-person MDPP services with the most recent attendance session of record
Beneficiary is in 2nd Year of MDPP set of Services when 1135 waiver event begins	Supplier suspends MDPP set of services during 1135 waiver event	N/A	**Option 1:** Beneficiary may resume the set of MDPP services with the most recent attendance session of record. OR **Option 2**: Beneficiary may restart the set of MDPP services at the ongoing maintenance interval in which s/he was participating at the start of the applicable 1135 waiver event.

Beneficiary MDPP Status	Supplier Response to 1135 Waiver Event	During 1135 Waiver Event	1135 Waiver event ends and in-person services resume
Beneficiary is in 2nd Year of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to switch to the virtual MDPP set of services. Once virtual services have started, the beneficiary may suspend virtual MDPP services at any time.	**Option 1**: Beneficiary may continue receiving services virtually until the conclusion of their services. OR **Option 2**: Beneficiary may resume the set of in-person services with the most recent attendance session of record. If the beneficiary received any part of the MDPP set of services virtually during an applicable 1135 waiver event, s/he cannot restart the set of MDPP services at the ongoing maintenance interval in which s/he was participating at the start of the applicable 1135 waiver event.
Beneficiary is in 2nd Year of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to suspend in-person MDPP set of services and does not switch to virtual MDPP services.	**Option 1**: Beneficiary may resume the set of MDPP services with the most recent attendance session of record. OR **Option 2**: Beneficiary may restart the set of MDPP services at the ongoing maintenance interval in which s/he was participating at the start of the applicable 1135 waiver event.
Beneficiary starts MDPP set of Services during an 1135 Waiver Event	Supplier offers to start new cohorts using virtual delivery of MDPP during 1135 waiver event	Beneficiary enrolls in MDPP and receives virtual delivery of MDPP services. Once virtual services have started, the beneficiary may suspend virtual MDPP services at any time.	**Option 1**: Beneficiary may continue receiving services virtually until the conclusion of their services. OR **Option 2**: Beneficiary may resume the set of in-person services with the most recent attendance session of record. If beneficiary received any part of the MDPP set of services virtually during an applicable 1135 waiver event, s/he cannot restart the set of MDPP services.

In addition, the rule permits MDPP suppliers to start new cohorts during the PHE for COVID–19 and any future applicable 1135 waiver events as long as

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a weight measurement for MDPP beneficiaries in the cohort can be obtained during the first core session. We proposed additional methods by which MDPP suppliers may obtain weight measurements from MDPP beneficiaries by allowing MDPP suppliers to obtain weight measurement from MDPP beneficiaries either in-person or via the use of technology, such as a Bluetooth-enabled scale or self-reported weight measurements using the MDPP beneficiary's digital scale and photograph or video technology.

Finally, taking into account comments concerning beneficiaries' access to scales that transmit weights securely via wireless or cellular transmission (commonly referred to as ''Bluetooth™ enabled'' or phones with video capabilities we are modifying proposed § 410.79(e)(3)(iii)(C) to allow MDPP suppliers to accept self-reported MDPP beneficiary weight measurements via a photograph with time stamp of their digital scale. When appropriate, in accordance with the §§ 414.84 and 410.79, MDPP suppliers may use the weight measurements obtained through any of the methods outlined in § 410.79(e)(3)(iii)(C) to submit claims to CMS for reimbursement for the first core session and any weight-loss based performance goals achieved during the set of MDPP services. Collectively, the flexibilities permitted during the PHE for COVID–19 or other applicable 1135 waiver events will allow beneficiaries with options to access the set of MDPP services in a manner that best suits their particular circumstances.

Comment: Several commenters supported our proposal to allow MDPP suppliers the option to deliver sessions virtually, or to suspend in-person services and resume in-person services at a later date. These commenters also supported the proposal that the limit placed on the number of virtual make-up sessions would not apply during the remainder of the PHE for COVID–19 or during any future applicable 1135 waiver events, and the proposed waiver of the once per lifetime limit that is applicable during the PHE for COVID–19 or an applicable 1135 waiver event. Multiple commenters urged CMS to remove the once-per-lifetime limit for MDPP services altogether and the 5 percent weight loss requirement for the ongoing maintenance period in Year 2. One commenter opposed ending the waiver of the minimum weight loss requirement for the ongoing maintenance sessions during applicable 1135 waiver events. They indicated that more individuals are struggling with weight loss/maintenance for many reasons. For example, many are not able to attend gyms or engage in other physical activity that puts them at risk for infection. These commenters stated that during the PHE for COVID–19, beneficiaries may not have the transportation options to travel to areas with healthy food options. One commenter encouraged CMS to continue this flexibility until July 2021 at a minimum to account for the next wave of the virus, combined with uncertainty in our economy, reopening, and the availability of a vaccine. Another commenter expressed concern about the ongoing health disparities during the PHE for COVID–19 in relation to a beneficiary's ability to meet the 5 percent weight loss requirement, referencing stress and anxiety that may have significant effects on weight loss. Another commenter advocated that the final rule not require beneficiaries to meet eligibility requirements for MDPP services again, regardless of whether they restart at the beginning or resume with the most recent attendance session of record. For an example, if a beneficiary lost weight or reduced their A1C or blood glucose value from MDPP class participation prior to the PHE, then under the proposed rule, they might not be eligible to restart MDPP when the PHE ends because they no longer meet the eligibility requirements.

Response: The provisions we are finalizing in this rule are intended to ensure that MDPP services can continue to be delivered during the remainder of the PHE for COVID–19 and any future applicable 1135 waiver events. We agree that the PHE for COVID–19 presents unique challenges to beneficiaries in terms of meeting and maintaining a 5 percent weight loss. However, the provisions we are finalizing in this rule permit virtual delivery of services, the virtual collection of body weight measurements, and provide access to appropriate beneficiary incentives, which collectively provide sufficient flexibilities to give MDPP beneficiaries the skills to successfully achieve the 5 percent weight loss goal. MDPP beneficiaries receiving the set of MDPP services prior to January 1, 2021 will not need to meet the 5 percent weight loss goal to resume the set of MDPP services with the most recent attendance session of record or to continue into the second year of set of MDPP services. Beneficiary eligibility will not be impacted by any changes to the beneficiary's body mass index (BMI) or reduction in hemoglobin A1c, fasting plasma glucose, or 2-hour plasma glucose test values achieved during the set of MDPP services or the intervening time in which a beneficiary has suspended the set of MDPP services. Beneficiaries who elect to suspend MDPP services may restart or resume services as described in the rule. Beneficiaries are eligible to restart or resume services regardless of their weight measurement or glucose level as of the date on which they elect to restart or resume services. Beneficiaries are encouraged to continue practicing the skills they have learned in the set of MDPP services to maintain a healthy lifestyle until they can restart or resume services.

Effective January 1, 2021, the 5 percent weight loss eligibility waiver described in § 410.14(g)(3)(iv) will end for MDPP beneficiaries starting after this date. However, the 5 percent weight loss eligibility waiver will remain in effect for MDPP beneficiaries who were receiving the set of MDPP services prior to January 1, 2021. MDPP beneficiaries who were receiving MDPP services prior to January 1, 2021 are not required to meet or maintain a 5 percent weight loss to maintain eligibility for the ongoing maintenance year and may resume or restart services without meeting the 5 percent weight loss requirement.

However, MDPP beneficiaries who start the set of MDPP services on or after January 1, 2021 will be required to meet and maintain the 5 percent weight loss goal to be eligible for the ongoing maintenance year described in § 410.79(c)(1)(ii)(B) and (c)(1)(iii)(B). The waiver of the requirement for beneficiaries to achieve 5 percent weight loss was intended to be a temporary flexibility to account for various state and local lock-down orders that prevented MDPP suppliers from obtaining weight measurements from beneficiaries to verify eligibility. The flexibilities we are finalizing in this final rule establish new remote and virtual methods for obtaining weight measurements. As such, the waiver of the 5 percent weight loss requirement is no longer necessary for the administration of the MDPP set of services. We are finalizing this policy as proposed.

When submitting claims to CMS for MDPP services, MDPP suppliers should use the following weight measurements as the baseline weight for purposes of determining all weight-loss achievements: For an MDPP beneficiary who began receiving the set of MDPP services before March 31, 2020, has suspended services during an applicable 1135 waiver event, and then elects to restart the set of MDPP services at the first core session, the MDPP supplier must record a new baseline weight on the date of first core session that restarts

the set of MDPP services. For an MDPP beneficiary who began receiving the set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, and then resumes the set of MDPP services either as the most recent attendance session of record or during the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session. For MDPP beneficiaries who were receiving MDPP services prior to January 1, 2021, as noted previously, the waiver of the 5 percent weight loss requirement still applies, so MDPP suppliers should submit a claim during each interval of the ongoing maintenance sessions in which the beneficiary has attended two sessions using the ''Attend 2 sessions (with at least 5% WL)'' HCPCS/G-codes.

Comment: One commenter stated that CMS' proposed policy of not allowing beneficiaries who elect to receive MDPP services virtually to restart the set of MDPP services at a later date is too restrictive. The commenter stated that this provision will contribute to health disparities because not all beneficiaries will be able to engage successfully in virtual MDPP sessions, such as issues with technology or internet connections. The commenter requested more flexibility in this policy and recommended that CMS allow beneficiaries who elect to receive MDPP services virtually retain eligibility to participate in in-person MDPP services after the end of the PHE for COVID–19 or applicable 1135 waiver event. The commenter also requested that CMS provide the opportunity to change an election if an applicable 1135 waiver event extends beyond a certain length (for example, greater than 6 months). Another commenter stated that there are many scenarios where an MDPP beneficiary would elect to receive virtual services but due to unforeseen circumstances those virtual session were not of a quality to impart the benefit of MDPP (for example, issues with technology, smart phone/computer availability, bandwidth). The commenter indicated many accounts from MDPP suppliers working in the field about in-person sessions that were moved to virtual sessions; some MDPP beneficiaries ''stuck with it'' while the barriers were too much for others and they had to drop out.

Response: We agree that prohibiting beneficiaries who elect to receive MDPP services virtually to restart the set of MDPP services at a later date is too restrictive. As such, we are amending our policy to allow MDPP beneficiaries receiving the MDPP set of services virtually, to suspend MDPP services and later resume the set of in-person MDPP services with the most recent attendance session of record once in-person services are available. However, we note that MDPP beneficiaries who opt to receive the set of MDPP services virtually during an applicable 1135 waiver event cannot repeat the set of MDPP services at a later date, in accordance with the general once per lifetime limitation for the set of MDPP services established in § 410.79(c)(1)(i)(B).

Comment: One commenter supported our proposal to allow MDPP suppliers to suspend in-person delivery of the set of MDPP services as necessary and resume upon the effective end date of the applicable 1135 waiver event or the date that CMS determines the 1135 waiver event no longer disrupts in-person MDPP services. The commenter requested additional flexibilities to accommodate a PHE or 1135 waiver event that may affect different populations of individuals, states or regions in different ways, with different timelines. The commenter stated that when CMS makes such a determination, the consequences may not only be different across regions/communities but may affect beneficiaries at both the cohort and individual level. The commenter expressed concern that CMS's decision could be arbitrary as it applies to a specific community. For example, if an MDPP beneficiary completes two virtual sessions but then may be required to return to in-person sessions before it is safe to do so in their area. The commenter recommended that CMS allow MDPP beneficiaries engaged in a virtual cohort of MDPP beneficiaries to continue virtual sessions until the end of the cohort, and not mandate a return to in-person MDPP services for cohorts in progress. The commenter also requested more clarification of how CMS will determine an applicable 1135 waiver event no longer disrupts in-person MDPP services. Another commenter requested a grace period to allow time for MDPP suppliers to transition back into providing in-person services.

Response: We agree that the impact of an applicable 1135 waiver event on in-person MDPP services can vary by population and locations. We disagree that decisions regarding the timeline to return to in-person services would be an arbitrary decision made by CMS. The emergency period is defined in section 1135(g) of the Act and in general, the emergency period for an 1135 waiver event lasts until the affected geographic area is substantially recovered from the event. In response to these comments, we are making one modification to the proposed provisions outlined in the proposed rule to address the concerns about the return to in-person services at the end of an applicable 1135 waiver event. During the PHE for COVID–19 or any future applicable 1135 waiver event, we will allow beneficiaries who switch to virtual MDPP or begin the set of MDPP services virtually to elect to continue receiving services virtually until the conclusion of their services. Our prior policy that MDPP is primarily an in-person service has had to be modified to accommodate the nature and length of the current PHE for COVID–19. While MDPP is still primarily an in-person service, allowing MDPP beneficiaries who switch to or begin the MDPP set of services virtually during an applicable 1135 waiver event to continue receiving the services virtually will allow the MDPP beneficiaries affected by an applicable 1135 waiver event to receive the set of services in a consistent modality. In response to the comment requesting a grace period after the end of the applicable 1135 event, we do not believe that an additional grace period would be necessary in most cases, given that the emergency period of an 1135 waiver event typically lasts for a duration that would permit affected providers to resume normal operations. However, we provided in our proposed regulation text at § 410.79(e)(3)(v) that MDPP suppliers could suspend in-person delivery of the set of MDPP services until the effective date of the 1135 waiver event (that is, the end of the emergency period under section 1135(g) of the Act) or upon a date specified by CMS. Therefore, our proposed regulation text contemplated that we could provide a grace period beyond the end of the emergency period. We anticipate that we would grant a grace period, which we would anticipate would not be longer than 90 days after the end of emergency period, if an MDPP supplier can demonstrate that it needs additional time to resume in-person services for reasons related to health, safety, or side availability or suitability. These flexibilities recognize that the effects of the PHE for COVID–19 or future applicable 1135 waiver events can vary in intensity based on location.

Comment: One commenter stated that their MDPP coaches have shared that many beneficiaries do not have video capability. Several commenters requested that beneficiaries be able to send in a photo of their weight

measurement instead. The commenter also expressed concerns with requesting a weight via email, which may not be compliant with HIPAA, and that requiring printed or faxed documentation will be a barrier for participants, because many people do not have access to printing or faxing when participating in the MDPP set of services from home.

Response: We agree that some MDPP beneficiaries may lack the technology required to provide a video or live feed of their weight measurement. In response to these comments, we are modifying the allowable weight measurement methodologies to include photo documentation. This final rule broadens the methods by which MDPP suppliers may obtain weight measurements from MDPP beneficiaries by allowing MDPP suppliers to obtain weight measurement from MDPP beneficiaries either in-person or via the use of technology, such as a Bluetooth-enabled scale or self-reported weight measurements using the MDPP beneficiary's digital scale and video technology. We are modifying proposed § 410.79(e)(3)(iii)(C) to allow MDPP suppliers to accept self-reported MDPP beneficiary weight measurements via a date stamped photograph or video recording of the beneficiary's weight with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session. A beneficiary may communicate his/her own information to a provider without violating the Health Insurance Portability and Accountability Act (HIPAA). Beneficiaries who are not comfortable transmitting their health information in this format can choose to suspend the set of MDPP services until in-person services are available. We encourage suppliers to utilize HIPAA compliant communication platforms. However, it is the organization's responsibility to comply with any federal, state, and/or local laws governing individual-level identifiable data, including those laws related to HIPAA, data collection, data storage, data use, and disclosure.

Comment: One commenter urged CMS to reconsider the timeframe for which flexibilities under the March 31st COVID–19 IFC are available. The commenter stated that there are MDPP beneficiaries who began receiving services between March 1, 2020, and March 15, 2020 because state timelines for shelter-in-place requirements varied across the country, but that most requirements were effective as of March 15, 2020. The commenter requested clarification that the flexibilities available under this final rule include participants who began the MDPP set of services between March 1 and March 15, 2020. This commenter also requested greater clarification between the requirements for beneficiaries who are in the ongoing maintenance phase of the MDPP set of services during the PHE for COVID–19 and any future 1135 waiver events, and questioned whether beneficiaries have until December 31, 2020 to restart the program, or if after that date, such beneficiaries will no longer have that flexibility.

Response: We agree with the commenter's recommendation. In response, we have made a modification to the regulation text at proposed § 410.79(e)(3)(v)(A) to specify that any beneficiary who began MDPP services on or before March 31, 2020—the effective date of the March 31st COVID–19 IFC—can elect to restart the set of MDPP services at the beginning or resume with the most recent attendance session of record upon the MDPP supplier's resumption of services. The modification to the date will extend the March 31st COVD–19 IFC flexibilities to all MDPP beneficiaries who started the MDPP set of services prior to the effective date of the March 31st COVID–19 IFC.

To clarify the requirements for MDPP beneficiaries who are in the ongoing maintenance phase: MDPP beneficiaries enrolled in the set of MDPP services prior to January 1, 2021 will not need to meet the 5 percent weight loss eligibility requirement to resume the set of MDPP services.

Effective January 1, 2021, the 5 percent weight loss eligibility waiver described in § 410.14(c)(3)(vi) will end for all MDPP beneficiaries starting after this date. However, the 5 percent weight loss eligibility waiver will remain in effect for MDPP beneficiaries who were receiving the set of MDPP services prior to January 1, 2021. MDPP beneficiaries who were receiving MDPP services prior to January 1, 2021 are not required to meet or maintain a 5 percent weight loss to maintain eligibility for the ongoing maintenance year and may resume or restart services without meeting the 5 percent weight loss requirement. However, MDPP beneficiaries who start the set of MDPP services on or after January 1, 2021 will be required to meet and maintain the 5 percent weight loss goal to be eligible for the ongoing maintenance year described in § 410.79(c)(1)(ii)(B) and (c)(1)(iii)(B).

The changes we are adopting in this final rule are effective January 1, 2021 and apply to the remainder of the PHE for COVID–19 and any future applicable 1135 waiver event. This means that MDPP beneficiaries who were receiving MDPP services as of March 31, 2020 may elect once to restart the set of MDPP services at the first core session, or resume in-person with their most recent session attendance of record as a result of the PHE for COVID–19 once at any time during the remainder of their set of MDPP services. However, MDPP beneficiaries who begin the set of MDPP services on or after January 1, 2021 will only be permitted to elect to restart the program at the first core session during the first 12 months of the set of MDPP services (and only if they do not switch to virtual MDPP services, if offered, during the applicable 1135 waiver event). MDPP beneficiaries who have restarted the set of MDPP services as a result of the PHE for COVID–19, and reside in an area that is subsequently impacted by a future 1135 waiver event, may elect to suspend in-person services, switch to virtual services, and restart or resume in-person services as provided in this rule.

Comment: One commenter supported the proposal to clarify that all MDPP sessions, including the first core session, may be offered virtually, not as ''virtual make-up sessions,'' but as virtual classes consistent with the in-person class curriculum. The commenter requested that CMS work with CDC on how MDPP suppliers should report this delivery type to the CDC, given that CDC has instructed in-person MDPP suppliers to report session delivery as virtual make-up sessions.

Response: In accordance with this rule, all MDPP sessions may be offered virtually, including the first core session, during an applicable 1135 waiver event. MDPP suppliers may also furnish virtual make-up sessions consistent with the § 410.79(d). All claims submitted to CMS for payment for MDPP services delivered virtually must include the Virtual Modifier ''VM'' on the claims submission form. We will work with CDC to ensure clarity and alignment for MDPP suppliers when reporting session delivery type to CDC.

Comment: One commenter suggested the following additional changes to the MDPP expanded model: (1) Address regulatory barriers to organizations becoming suppliers, including the requirement for Medicare suppliers to submit Social Security Numbers (SSN) to CMS, which raises privacy concerns for some organizations, and has resulted in some organizations choosing not to move forward with Medicare supplier enrollment; (2) revise the reimbursement structure to front-load

payments to ensure suppliers' upfront costs of serving the Medicare population, given that many MDPP suppliers are community-based organizations with scarce resources to wait for outcomes-based payments; (3) align the program model with the model test and the evidence, which would result in changing MDPP to a 1-year model that aligns with the CDC's NDPP curriculum; and (5) address special populations to avoid cherry picking, taking into account the socioeconomic barriers that prevent low-income individuals from achieving the full 5 percent weight loss required for ongoing maintenance services. The commenter requested that CMS offer modest relief from the 5 percent weight loss requirement, or provide payment adjustments to enable MDPP suppliers to address barriers beneficiaries face to participating in MDPP, such as a lack of transportation.

Response: We appreciate the commenter's recommendations but they are outside the scope of this final rule. We will consider these recommendations in the future.

After consideration of the comments received, we are finalizing our proposals with the following modifications:

- We will add allowable virtual weight measurement methods. In addition to the methods proposed, MDPP beneficiaries may self-report their weights in the following ways: By submitting a time and date-stamped photo or video of their home scale with their current weight measurement, or by using synchronous, online video technology such as video chatting or video conferencing with an MDPP coach, where the coach can clearly observe the self-recorded weight of the beneficiary. The second change is ensuring that flexibilities initially finalized in the March 31st COVID–19 IFC (85 FR 19230) are extended to all beneficiaries who were receiving MDPP services as of March 31, 2020, in order to include those beneficiaries who started MDPP services in the month of March, given that state shelter-in-place orders varied significantly.
- We will allow beneficiaries who begin the set of MDPP services virtually, or who change from in-person MDPP services to virtual during the PHE for COVID–19 or an applicable 1135 waiver event, to continue the MDPP set of services virtually, even after the PHE or 1135 waiver event has concluded.
- We added § 410.79(e)(3)(v)(B) to the rule to clarify the baseline weight measurement that must be used by an MDPP supplier when an MDPP beneficiary restarts or resumes the set of MDPP services following a suspension in services.
- We are updating the cross reference, § 410.79(e)(4)(iii), found in the proposed rule in paragraph (e)(3)(ii) to correctly reflect the proper cross reference at paragraph (e)(3)(iii).
- We are making a few edits for technical clarity. We edited the proposed paragraph (e)(3)(v) to remove the phrase ''must be furnished in compliance with the requirements in accordance with'' and will replace it with ''must be furnished in accordance with.'' We edited paragraphs (e)(3)(v)(B) and (C) to include ''and who elect not to continue with MDPP services virtually.'' In addition, we edited paragraph (e)(3)(v)(D) to improve the clarity.
- Finally, we did not intend to eliminate the waiver as specified in paragraph (e)(3)(iii), of the minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) for MDPP beneficiaries who were receiving the MDPP set of services prior to January 1, 2021. As such we have added the language into the final rule, redesignted as paragraph (e)(3)(vi)

2. Revisions to § 424.210

Under § 424.210(b), an MDPP supplier may furnish in-kind beneficiary engagement incentives to an MDPP beneficiary if certain requirements are satisfied. Among other requirements, the in-kind item or service must be furnished only during the ''engagement incentive period.'' The definition of ''engagement incentive period'' at § 424.210(a) states that the period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary, and it ends on the earliest of the following: (1) When the MDPP services period ends as described in § 410.79(c)(3); (2) when the MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier; or (3) the MDPP supplier has not had direct contact, either in-person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period. We recognize that the disruption to MDPP services caused by an applicable 1135 waiver event may cause an MDPP supplier not to have contact with an MDPP beneficiary for more than 90 consecutive calendar days. Therefore, we proposed to amend the definition of ''engagement incentive period'' to further qualify when the period ends in the case of the PHE for COVID–19 or an applicable 1135 waiver event. Specifically, we proposed to amend paragraph (iii) in the definition of ''engagement incentive period'' to state that the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period, unless the lack of direct contact is due to the suspension or cancellation of MDPP services under § 410.79(e) and the MDPP services are eventually resumed or restarted in accordance with § 410.79(e).

We solicited comments on when the engagement incentive period should end if the MDPP services are not eventually resumed. We noted that we were considering whether we should deem the incentive engagement period to end if the applicable 1135 waiver event or the PHE for COVID–19 remains in effect for a certain period of time, such as 1 year. At that point, for purposes of beneficiary engagement incentives, it may be more appropriate to terminate the engagement incentive period and permit a new engagement incentive period to begin if services are resumed or restarted in accordance with § 410.79(e). Alternatively, we noted that the engagement incentive period can also end when the MDPP supplier knows that the MDPP beneficiary will no longer be receiving services from the MDPP supplier. We solicited comments on whether that provision eliminates any need to further clarify in regulation text when the engagement incentive period ends if MDPP services are not eventually resumed or restarted.

We also proposed to amend § 424.210(b) to add a requirement governing the provision of an in-kind item or service as a beneficiary engagement incentive during the PHE for COVID–19 or during an applicable section 1135 waiver event. Specifically, we proposed that if the item or service is furnished during the PHE for COVID–19 or an applicable 1135 waiver event that CMS has determined may disrupt in-person MDPP services, and the item or service is furnished to an MDPP beneficiary who is receiving MDPP services virtually, the MDPP beneficiary must be capable of using the item or service during the PHE for COVID–19 or the applicable 1135 waiver event, as applicable. We proposed this usability requirement to deter abuse and to ensure that the incentives furnished during an applicable 1135 waiver event will achieve their intended purpose and serve the goals of the MDPP expanded model. We stated that usable beneficiary engagement incentives would include

vouchers for healthy food, wearable technology or ''wearables'' used to monitor an MDPP beneficiary's health such as heart rate, calories burned, or steps walked. We also noted that gym memberships during lockdowns and stay-at-home orders would not constitute beneficiary engagement incentives that are usable during an applicable 1135 waiver event. We solicited comments on whether this additional requirement is necessary in light of other requirements set forth in § 424.210(b).

Finally, for purposes of the proposed usability requirement at § 424.210(b)(9), we proposed to define ''COVID–19 Public Health Emergency'' to mean the emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, related to the PHE for COVID–19 declared by the Secretary on January 31, 2020. Effective October 23, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE exists and has existed since January 27, 2020. Similarly, we proposed to define ''1135 waiver event'' to mean an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized waivers under section 1135 of the Act. We noted that these definitions were consistent with how we proposed to define the terms for purposes of § 410.79(e).

The following is a summary of the public comments we received and our responses.

Comment: One commenter appreciated the flexibility of the proposed change to paragraph (iii) of the definition, indicating that the engagement incentive period should not automatically end if an MDPP supplier's failure to have direct contact with an MDPP beneficiary for more than 90 days was due to the suspension or cancellation of MDPP services during an applicable 1135 waiver event and the MDPP services were resumed during such 1135 waiver event. The commenter stated that the final rule should clarify when the engagement incentive period ends if MDPP services are not eventually resumed. The commenter supported the addition of a provision under which the engagement incentive period would be deemed to end if MDPP services are not resumed or restarted within 1 year after the PHE for COVID–19 or applicable 1135 waiver event has been in effect. The commenter also stated that, if MDPP services are thereafter resumed or restarted, CMS should permit a new engagement incentive period to begin.

Response: After further consideration, we are not finalizing the proposed changes to paragraph (iii) of the definition of engagement incentive period. That provision will continue to specify that the engagement incentive period will end if the MDPP supplier has not had direct contact with the MDPP beneficiary, whether in person, by telephone, or via other telecommunications technology, for more than 90 consecutive calendar days during the MDPP services period. Under this provision, the engagement incentive period will not end with respect to an MDPP beneficiary who begins to receive MDPP services virtually within 90 days after the occurrence of an 1135 waiver event that CMS determines is likely to disrupt the furnishing of in-person MDPP services. We are mindful of the potential for abuse with beneficiary incentives, and in the absence of any continued direct contact with the MDPP beneficiary for 90 days during an applicable 1135 waiver event, we do not believe that the MDPP supplier should be permitted to furnish additional beneficiary engagement incentives. However, we note that the existing definition of engagement incentive period specifies that the period begins ''when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary.'' Accordingly, even if an MDPP beneficiary's engagement incentive period ends during an applicable 1135 waiver event due to lack of direct contact with the MDPP supplier, the beneficiary would begin a new engagement incentive period consistent with the existing definition when he or she resumes or restarts MDPP services in accordance with § 410.79(e).

Comment: One commenter stated that revising the definition of engagement incentive period as proposed would increase the recordkeeping and tracking burden on MDPP suppliers, who the commenter asserted will need to track the start and end dates of the PHE or 1135 waiver event, the election of the MDPP beneficiary to suspend or cancel MDPP services, the date of the resumption or restart of services, and more. The commenter requested that CMS specify the documentation and tracking requirements for this change.

Response: As noted above, we are not finalizing the proposed changes to the definition of engagement incentive period. We did not propose and are not finalizing any modifications to the documentation requirements described in § 424.210(e). However, we note that § 424.210(e) requires MDPP suppliers to maintain documentation regarding in-kind items and services furnished as beneficiary engagement incentives, including the date on which the item or services was furnished and whether it was furnished during the engagement incentive period. In addition, it is a prudent business practice to document compliance with Medicare regulations, and the information cited by the commenter would be relevant to compliance with § 410.79 and § 424.210.

Comment: One commenter did not believe that the usability requirement at proposed § 424.210(b)(9) was necessary considering the other requirements set forth in § 424.210(b), but stated that if the requirement is retained in the final rule, it should be revised for clarity. Specifically, this commenter questioned whether a beneficiary engagement incentive that is furnished during an 1135 waiver event must be usable by the MDPP beneficiary for the remaining duration of the 1135 waiver event or only at the time the incentive is furnished. As an example, the commenter noted that an MDPP supplier might provide a gym membership voucher during an 1135 waiver event at a time when gyms are open, but the membership could become unusable at a later time during the 1135 waiver event. The commenter advocated that if the final rule includes a requirement regarding the usability of an incentive during the PHE for COVID–19 or an 1135 waiver event, the requirement should expressly state that the MDPP beneficiary must be capable of using the item or service ''at the time of delivery.'' Another commenter requested clarification that that a gym membership would satisfy the proposed usability requirement even if it was furnished when a lockdown or stay-at-home order was in effect, as long as the gym offered virtual fitness classes. In addition, a commenter sought clarification that in-kind items or services that may be useable in one region may not be useable in another region. The commenter expressed concern that documenting compliance with the usability requirement would place undue burden on MDPP suppliers.

Response: Upon further review, we agree that the usability requirement is not necessary in light of other requirements set forth at § 424.210(b). Specifically, under paragraph (b)(2), the in-kind beneficiary engagement incentive must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, core maintenance session, or ongoing maintenance session. In addition, under paragraph (b)(3), the in-kind beneficiary engagement incentive must be a ''preventive care item or service'' or an

item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. We would not consider either of these requirements to be satisfied if the MDPP beneficiary is incapable of using the item or service at the time it is furnished. Accordingly, because an unusable in-kind item or service could not satisfy all of the conditions set forth at paragraph (b), it is not necessary to finalize the additional proposed requirement for in-kind items and services furnished to an MDPP beneficiary who is receiving MDPP services virtually during the PHE for COVID–19 or an 1135 waiver event. Because we are not finalizing the proposed usability requirement, the commenters' remaining concerns are moot and need not be addressed.

Comment: One commenter supported the proposed definitions of ''COVID–19 Public Health Emergency'' and ''1135 waiver event.''

Response: We appreciate the commenter's support. However, as finalized, § 424.210 does not refer to either term. Accordingly, we are not finalizing these definitions.

After consideration of the comments received, we are not finalizing the proposed usability requirement nor the proposed definitions of ''COVID–19 Public Health Emergency'' and ''1135 waiver event'' proposed at § 424.210(b).

IV. Summary of the Quality Payment Program Proposed Provisions, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

A. CY 2021 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the final rule sets forth changes to the Quality Payment Program starting January 1, 2021, except as otherwise noted for specific provisions. The 2021 performance period/2023 payment year of the Quality Payment Program continues a transition as we build on the first few years of implementation of the Quality Payment Program to focus better on our measurement efforts, and to reduce barriers to entry into Advanced APMs.

Participation in the Quality Payment Program rose in the third year. We saw 99.99 percent of eligible clinicians participate in MIPS in 2019 with 954,614 eligible clinicians receiving a payment adjustment, which exceeded our 2018 participation rates. In addition, 97.6 percent of eligible clinicians participating in MIPS received a positive payment adjustment for 2021 based on 2019 performance year results. Regarding performance in Advanced APMs, for the 2019 QP Performance Period, 195,564 eligible clinicians earned Qualifying APM Participant (QP) status while another 27,995 eligible clinicians earned partial QP status.[116] We note that due to the Public Health Emergency (PHE) for COVID–19, 65,237 (or about 6.83 percent of 954,614) MIPS eligible clinicians received reweighting for performance year 2019 of one or more MIPS performance categories due to our MIPS extreme and uncontrollable circumstances policy.

We plan to continue developing Quality Payment Program policies that more effectively reward high-quality treatment of patients and increase opportunities for Advanced APM participation. We are moving forward with MIPS Value Pathways (MVPs) policy development as MVPs allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population. The MVPs use promoting interoperability as a foundational element and incorporate population health claims-based measures as feasible along with relevant measures and activities for the quality, cost, and improvement activities performance categories. We intended to begin transitioning to MVPs in the 2021 MIPS performance year; however, due to the PHE for COVID–19 and resultant need for clinician focus on the response, our timeline changed accordingly such that the proposal for initial MVPs is delayed until at least the 2022 performance year. In addition, we support clinicians on the front lines by providing burden relief via extreme and uncontrollable circumstances policy exceptions for 2019, 2020 and 2021.

In response to the PHE for COVID–19, a number of additional flexibilities were issued via interim final rules with comment periods (IFCs) (85 FR 19276 through 19278, 85 FR 27617, and 85 FR 54847 through 54851). We extended the deadline for applying for reweighting due to extreme and uncontrollable circumstances for the 2019 performance period from December 31, 2019 to April 30, 2020 in order to provide greater flexibility for clinicians impacted by the PHE for COVID–19 and modified our existing policy for the 2019 performance period such that MIPS data submissions would not effectively void a reweighting application. We added a new ''COVID–19 Clinical Trials'' improvement activity to the CY 2020 Improvement Activities Inventory, applicable beginning January 2020 that would provide high-weighted credit in the Improvement Activities performance category and then modified the activity in the third IFC (March 31st COVID–19 IFC (85 FR 19276 through 19277)). We provided QCDRs an additional year, by 2022, to meet the QCDR measure requirements of measure testing and data collection. Due to COVID–19 we also modified our definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey to include online and telephone digital E/M codes, and remote evaluation of patient video/images and virtual check in codes. These included previously finalized ''face-face'' codes that are instead furnished using audio/video, real-time, interactive communications technology instead of in person in light of the PHE. We are finalizing all IFC policies except for the COVID–19 Clinical Trials activity for 2020, which is finalized with a modification as presented in the third IFC. See section IV.A.3.c.(3)(b) of this final rule for the modified COVID–19 Clinical Trials activity for CY 2020 as described in the September 2, 2020 IFC (85 FR 54848 through 54851).

As we make long-term improvements, evolve MIPS policies, and plan to implement MVPs in the future, we support our objectives within the Patients Over Paperwork initiative and the National Quality Roadmap.[117] [118] In carrying out these initiatives, we are removing regulatory obstacles that get in the way of health care clinicians spending time with patients. As we develop MVP policies, we look to reduce MIPS reporting burden and increase efficiencies.

On May 15, 2020 the Department of Health and Human Services published the National Quality Roadmap (*https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf*) as directed by E.O. 13877, Improving Price and Quality Transparency in American Healthcare to Put Patients First. The purpose of the Roadmap is to improve patient outcomes through enhanced effectiveness and efficiency of the healthcare quality system. The Roadmap is a means to accelerate change and advance the Administration's goals of ''improving transparency, reducing provider burden, allowing informed

[116] QPP Participation in 2019: Results at-a-Glance released 10/27/2020 at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1190/QPP%202019%20Participation%20Results%20Infographic.pdf.*

[117] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.*

[118] *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

consumer decision-making, and ultimately improving the health of all Americans''. The Roadmap, which provides a public-private partnership opportunity, describes a strategy for establishing, adopting, and publishing common quality measurements, aligning inpatient and outpatient measures, and eliminating low-value or counterproductive measures. Specific actions are identified to drive change through coordinated governance and oversight, modernized data collection and reporting, and aligned measures reformation in federal quality programs. One of the actions called for is a systematic review of federal quality reporting and value-based payment programs, to identify opportunities leading to recommendations to reduce burden, promote efficiency and effectiveness, and accelerate the shift to value. The Roadmap also calls for stakeholder engagement through public convening and a Request for Information. Actions will be undertaken with the underpinning of the following principles:

- Quality Information is Available and Meaningful.
- Balance Administrative Burden with the Goal of Obtaining Meaningful Information.
- Alignment of Measurement Priorities.
- Cohesive Measurement Stewardship.
- Reward Innovation and Improvement.
- Leverage What Works and Reform the Rest.

The planned implementation of MVPs is noted in the Roadmap and we look forward to recommendations resulting from other Roadmap activities for streamlining quality reporting and value-based purchasing programs that can inform the implementation of the MVPs and promote alignment of quality measures across federal programs.

As we work within MIPS to reduce barriers to clinician participation in Advanced APMs and meet CMS pay for value objectives, we are aligned with the Health Care Payment Learning & Action Network goal to accelerate the percentage of health care payments tied to quality and value in each market segment through the adoption of two-sided risk APMs.[119] MVPs will link quality and cost performance measurement and help clinicians begin to assess their ability to take on risk as in APMs.

In the May 1, 2020 **Federal Register**, HHS published two transformative rules: The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642 through 25961); and the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers final rule (85 FR 25510 through 25640) that will give patients unprecedented safe, secure access to their health data. The two rules implement interoperability and patient access provisions of the bipartisan 21st Century Cures Act (Cures Act) and support the MyHealthEData initiative. MyHealthEData is designed to empower patients around a common aim, giving every patient access to their medical information so they can make better healthcare decisions. We expect that these rules, once implemented, will complement our future MVPs in providing more meaningful information to clinicians and patients.

b. Summary of Major Provisions

(1) Major MIPS Provisions

The MIPS program aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. Within MIPS we intend to pay for health care services in a way that drives value by linking performance on cost, quality, and the patient's experience of care. We believe implementing the MVP framework will move MIPS along the ''path to value,'' transforming the MIPS program by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes, and by promoting robust and accessible healthcare data, and interoperability. In the CY 2020 PFS proposed rule (84 FR 40732 through 40745), we offered our vision of an MVP framework for a new evolution of the MIPS program based on this concept.

As discussed in the CY 2021 PFS proposed rule at 85 FR 50277, we have built the MIPS program to provide broad flexibility for clinician choice of measures and activities, data collection and submission types, and individual or group level participation. While these flexibilities contributed to very high participation levels, we believe the flexibility has inadvertently resulted in a complex MIPS experience for clinicians that is not producing the level of robust clinician performance information we envision that would meet patient needs and support clinician care improvements. We have heard from clinicians that MIPS requirements are confusing, burdensome, and that it is difficult to choose measures from the several hundred MIPS and QCDR quality measures that are meaningful to their practices and have a direct benefit to patients. We have also heard concerns from stakeholders that MIPS does not allow for sufficient differentiation of performance across practices due in part to clinician quality measure selection bias. These aspects detract from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. MVPs are intended to lead to a simplified MIPS clinician experience, improve value, reduce burden, and better inform patient choice in selecting clinicians. We noted that the MVP framework would connect measures and activities across the 4 MIPS performance categories, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. We intend to focus the future of MIPS on MVP implementation. We are finalizing proposed provisions as discussed in section IV.A.3. of this final rule related to:

- Developing MVPs
- Implementing the APM Performance Pathway (APP) for APM participant MIPS eligible clinicians to report to MIPS
- Updating the MIPS performance measures and activities; cost and quality category weights; and scoring policies
- Terminating the APM scoring standard.

(a) MIPS Value Pathways and APM Performance Pathway

We are finalizing the proposed MVP framework guiding principles as discussed in section IV.A.3.a.(1) of this final rule and the proposed MVP development criteria and processes as discussed in section IV.A.3.a.(2) of this final rule as we look towards the 2022 performance period to begin MVP implementation. We are finalizing in section IV.A.3.b. of this final rule each of the proposed quality measures included in the APP quality measure set effective January 1, 2021. We are also delaying the sunsetting of the CMS Web Interface by one year and allowing APM entities to report via the CMS Web Interface measure set for the 2021 MIPS

[119] *https://hcp-lan.org/.*

performance period. Submitters reporting through the APP will be scored on the ACO MCC measure, Hospital-wide Readmission measure, and CAHPS for MIPS survey, if available for that submitter type. In addition, each submitter will also be required to report on either the three eCQMs/MIPS CQMs or, for APM Entities, the Web Interface. The APP will be a voluntary pathway for reporting and scoring under MIPS that allows APM participants to receive an improvement activities credit and have the cost performance category reweighted. We are finalizing proposed MIPS performance category weighting and scoring in the APP and a scoring hierarchy that recognizes the APP in section IV.A.3.e.(2) of this final rule. We are also finalizing in section IV.A.3.c.(5)(a) of this final rule the elimination of the APM scoring standard for the 2021 performance year beginning January 1, 2021. This allows APM participants to participate in MIPS as individuals, groups, Virtual Groups, or APM Entities, with reporting through any MIPS reporting and scoring pathway, see section IV.A.3.b.(3) of this final rule. We are also finalizing in section IV.A.3.c.(5)(e) of this final rule, an extreme and uncontrollable circumstances exception policy proposal that would be applicable to APM Entities beginning with the 2022 MIPS payment year.

In response to our MVP RFI in the 2020 PFS proposed rule (84 FR 40732 through 40745), we received a number of comments about the opportunity to participate in the development of MVPs and concerns about the speed of a transition to a new MVP framework. We have taken these concerns into consideration when developing the proposed MVP policies. We had stated our intent to begin the transition to MVPs in 2021 by introducing initial MVPs, however, we noted at 85 FR 50284 through 50285 that due to the PHE for COVID–19, the timeline has changed. As we move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the PHE for COVID–19, we limited the MVP-related proposals to those necessary for the collaborative development of MVPs.

We are finalizing in section IV.A.3.a.(2) of this final rule, the proposed process for collaboration on the development of MVPs that builds on our discussions with clinician experts about developing MVPs for future MIPS rulemaking. We believe that collaboration with clinician experts will build a more cohesive and comprehensive set of MVPs. We are finalizing the proposed process for MVP candidate submissions in section IV.A.3.a.(2)(a)(iii) of this final rule.

We recognize that the transition to MVPs will take time and we will continue to evaluate the readiness of clinicians in making this transition, while balancing our strong interest in improving measurement and making MIPS more focused on value.

(b) Other MIPS and APM Policies

We are finalizing with modification our web interface and quality measure proposals as discussed in sections IV.A.3.c.(1)(c) and IV.A.3.c.(1)(d) of this final rule, respectively, after consideration of comments. Additionally, are finalizing in section IV.A.3.d.(1)(b) of this final rule the proposed continuation of policies for scoring quality measures based on achievement, as well as policies for measures that do not meet case minimum, data completeness requirements, or have a benchmark. For the Promoting Interoperability performance category, we are finalizing the proposed new optional Health Information Exchange (HIE) bi-directional exchange measure as discussed in section IV.A.3.c.(4)(c)(ii)B of this final rule.

Additionally, after considering public comments, we are finalizing the following provisions for MIPS beginning with the 2021 performance period in this final rule.

- As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing our proposal to remove the CMS Web Interface submission method under MIPS for groups and virtual groups with a one year delay. Specifically, we will sunset the Web Interface in 2022 instead of 2021.
- As discussed in section IV.A.3.c.(1)(d) of this final rule, we are finalizing the proposals to incorporate 2 new administrative claims outcome quality measures, address substantive changes to 112 existing MIPS quality measures, address changes to specialty sets, remove measures from specific specialty sets. We are finalizing a modified proposal to remove 11 instead of 14 quality measures from the MIPS program. We refer readers to Table Group C of Appendix 1 for a list of final quality measures and further information. Retaining three additional measures means that we are finalizing a modified proposed total of 209 rather than 206 quality measures starting in the 2021 performance year.
- As discussed in sections IV.A.3.c.(1)(e) and IV.A.3.c.(2)(b) of this final rule, we are finalizing the proposals to include services provided via telehealth in quality and cost measurement.
- As discussed in section IV.A.3.c.(2)(a) of this final rule, we are finalizing the proposals that the cost performance category will make up 20 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act, and the quality performance category weight will be 40 percent and 30 percent for each of those years, respectively (see section IV.A.3.c.(1)(b) of this final rule). For the 2023 MIPS payment year, we are finalizing the proposed performance category redistribution policies discussed in section IV.A.3.d.(2)(b)(iii) of this final rule.
- As discussed in section IV.A.3.c.(3)(b) of this final rule, we are finalizing our proposals to: (1) Allow an exception to the Annual Call for Activities nomination period timeframe during a PHE; (2) add a new criterion for nominating new improvement activities; (3) implement a process for HHS-nominated improvement activities; and (4) modify two existing improvement activities. We are also finalizing policies from IFCs and the removal of one obsolete improvement activity and policies from IFCs.
- As discussed in section IV.A.3.c.(4) of this final rule, we are finalizing the proposals that establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year, for the 2024 MIPS payment year and each subsequent MIPS payment year; update two Promoting Interoperability measures; and continue reweighting the Promoting Interoperability performance category for non-physician MIPS eligible clinicians for the 2021 performance period. We are finalizing at section IV.A.3.c.(4)(c)(ii) of this final rule the proposal to add a new Promoting Interoperability performance category Health Information Exchange (HIE) bi-directional exchange measure that would allow an eligible clinician to attest to participation in bi-directional exchange through an HIE using CEHRT functionality.
- As discussed in section IV.A.3.d.(1)(b) of this final rule, we are finalizing the proposed continuation of quality category scoring and bonus policies that add flexibility for when measure specification or coding changes occur during the performance year and continue improvement scoring of the

quality performance category comparing clinicians to a 30 percent baseline score if clinicians scored 30 percent or less. We are finalizing in section IV.A.3.d.(1)(b)(iii) of this final rule the proposal for an exception to the 20-case minimum for all administrative claims-based measures. The exception states that for administrative claims-based measures, the minimum case requirement is specified in the annual list of MIPS measures.

• As discussed in section IV.A.3.d.(2)(a)(iii) of this final rule, we are finalizing the proposal to increase the maximum number of points available for the complex patient bonus for one year, the 2020 performance period/2022 MIPS payment year, due to the increase in patient complexity resulting from the PHE for COVID–19.

• As discussed in section IV.A.3.g. of this final rule, we are finalizing the proposals to modify third party intermediary requirements, remedial actions and termination policies. We are also finalizing policies issued via IFC.

• As discussed in section IV.A.4.b. and IV.A.4.c. of this final rule, we are finalizing the proposals that clarify the APM Incentive Payment amount calculation basis and implement a hierarchy for recipient TIN affiliation identification when making the APM Incentive Payment. We are also finalizing proposed provisions in section IV.A.4.c. of this final rule that provide a process for requesting updated APM Incentive Payment information in situations where a payee TIN cannot be identified, and address in section IV.A.4.d. of this final rule situations where the QP's APM Incentive Payment was determined based solely on supplemental services payments and no Medicare claims for covered professional services were submitted during the incentive payment base period.

• As discussed in section IV.A.4.e.(3) of this final rule, we are finalizing the proposed change to the methodology for addressing prospectively aligned beneficiaries for Threshold Score calculations and QP determinations and establish a targeted review process in section IV.A.4.e.(4) of this final rule for QP determinations.

After consideration of public comments, we are not finalizing the following proposals:

• As discussed in sections IV.A.3.d.(1)(b)(ii) and IV.A.3.d.(1)(b)(v) of this final rule, we are not finalizing using performance period benchmark policies for performance year 2021 and will instead continue with the existing policy to use historical benchmarks and our topped out scoring policy after considering comments and the impact of the PHE for COVID–19.

• As discussed in section IV.A.3.e.(3) of this final rule, we are not finalizing the proposal to reduce the performance threshold for the 2021 MIPS performance period/2023 MIPS payment year from 60 points to 50 points, as we believe that we best incentivize clinician performance through retaining the previously finalized performance threshold of 60 points.

2. Definitions

At § 414.1305, we are finalizing definitions of the following terms:

• Attestation (revision).
• Certified Electronic Health Record Technology (CEHRT) (revision).
• Collection type (revision).
• Full TIN APM (deletion).
• Low volume threshold (revision).
• Meaningful EHR user for MIPS (revision).
• MIPS APM (revision).
• Physician Compare (addition).
• Primary Care Services (addition).
• Submission type (revision).

These terms and definitions are discussed in detail in the relevant sections of this final rule.

3. MIPS Program Details

a. Transforming MIPS: MIPS Value Pathways

(1) Overview

We are finalizing proposed updates to the MIPS Value Pathways (MVP) guiding principles (see 85 FR 50280 through 50281) and MVP development criteria and process (see 85 FR 50281 through 50284) that will guide MVP implementation beginning with the 2022 MIPS performance period/2024 MIPS payment year.

In the CY 2020 PFS final rule, we stated our intent to apply the MVP framework in PY 2021 (84 FR 62946); however, due to the PHE for COVID–19, our timeline has changed (see 85 FR 50284 through 50285). We want to move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the PHE for COVID–19, and so have limited our MVP related proposals in this rule to guidance necessary for the collaborative development of MVPs. We deferred MVP implementation to a future year. In particular, we intend to propose an initial set of MVPs and implementation policies in our CY 2022 rulemaking cycle. We continue to envision a transformed MIPS program that increasingly makes MVPs available to clinicians with a burden reduction focus.

We intend to implement the MVPs while maintaining the MIPS participation options established through rulemaking for MIPS performance years 1 through 5. For purposes of this discussion, we refer to the established MIPS participation options collectively as ''traditional MIPS''.

As described in earlier rulemaking (84 FR 40732 through 40734), we are moving to MVPs to improve value, reduce burden, help patients compare clinician performance to inform patient choice in selecting clinicians, and reduce barriers to movement into APMs. We refer to ''value'' as a measurement of quality and patient experience of care as related to cost, and intend to promote value by paying for health care services in a manner that directly links performance on cost, quality, and the patient's experience of care. The MVP framework will move MIPS forward on the path to value through connecting the MIPS performance categories and by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability.

We believe that MVPs can help address previous feedback from clinicians that MIPS is too complex and burdensome. Feedback related to confusing MIPS requirements, inadequate alignment of the MIPS performance categories, need for better performance comparability across all clinicians and for more meaningful data for patients has informed development of the MVP framework. MVPs will make MIPS more meaningful by allowing a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a patient population, standardizing performance measurement of a specialty or a medical condition, and reducing the siloed nature of the traditional MIPS participation experience. We intend that MVPs help clinicians and practices prepare to take on and manage financial risk, as in Advanced APMs, as they build out their quality infrastructures that align with the MIPS performance categories and gain experience with cost measurement. Performance measure reporting for specific populations as in MVPs encourages practices to build an infrastructure with capabilities to compile and analyze population health data, a critical capability in assuming and managing risk. We believe that experience with MVPs, in which there is aligned measurement of quality (of care and of experience of care) and cost,

continuous improvement/innovation within the practice, and efficient management and transfers of information, will help remove barriers to APM participation. We refer readers to the infographic at *https://qpp.cms.gov/mips/mips-value-pathways*, which provides an overview of our vision for the MIPS path to value future state (see 85 FR 50279).

We envisioned that MVPs will be optional for clinicians when the included measures and activities within the MVP are applicable and available to their practice. Over the course of future performance periods as we transition to MVPs, the traditional MIPS participation option will continue to be available. We noted that we believe MVP reporting will reduce selection burden associated with choosing MIPS quality measures and activities to report; reduce reporting burden associated with fewer MIPS quality measures, cost measures and/or improvement activities to report than the traditional MIPS participation method; and further align across performance categories the measures and activities identified by specialists and patients as being meaningful and relevant. We noted that we intended to build a robust inventory of MVPs which are meaningful to clinicians and expect that in the future we may propose that all MIPS eligible clinicians would be required to participate in MIPS either through an MVP or an APM Performance Pathway (APP).

In the CY 2021 PFS proposed rule (85 FR 50280 through 50281), we proposed to update the MVP guiding principles from the CY 2020 PFS proposed rule (84 FR 40734) to incorporate RFI comments and the evolution of the MVP framework. We refer readers to the CY 2021 PFS proposed rule for a discussion of the RFI comments. We proposed to add a new fifth guiding principle pointing to an important Meaningful Measures element of our future vision for reducing MVP reporting burden; the use of digital performance measure data submission technologies to indicate our commitment to leveraging digital innovations that reduce MIPS related clinician burden. Digital Quality Measures (dQMs) originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems. We refer readers to the CY 2021 PFS proposed rule (85 FR 50280) for a discussion of dQMs. We proposed to retain guiding principle 4 (84 FR 40734) and update guiding principles 1, 2, 3 and 5, as shown in italics, so that the guiding principles for MVPs reflect the following:

1. MVPs should consist of limited, *connected complementary* sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, *align* scoring, and lead to sufficient comparative data.

2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; *MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.*

3. MVPs should include measures *selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included,* to encourage performance improvements in high priority areas.

4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

5. MVPs should support the transition to digital quality measures.

We described our proposed method of creating MVPs in the CY 2020 PFS proposed rule (85 FR 50281 through 50283). We noted that we intend to grow the number of available MVPs using the processes described in that section, maximizing our opportunity for expert input on the most meaningful measures and activities.

We noted that we continue our efforts to improve the healthcare of Medicare patients by allowing clinicians to focus on providing care for their patients and the measures and activities that best reflect their care. We also noted that we look forward to continuing to work with stakeholders to improve the program and implement the vision of MVPs.

We received public comments on this proposal. The comments we received and our responses are set forth below.

Comment: Many commenters supported the MVP guiding principles as proposed with some commenters voicing support for all the guiding principles and some commenters highlighting support for subsets of the guiding principles. Commenters voiced a number of reasons for their support of the guiding principles related to moving towards MVP goals of burden reduction, meaningful performance measurement, capturing the patient voice, and/or moving to higher value care.

Response: We appreciate the commenters' support of MVP guiding principles that will move us towards our goals of improving value, reducing burden, helping patients compare clinician performance to inform patient choice in selecting clinicians, and reducing barriers to movement into APMs. We agree with commenters that the MVP guiding principles will help realize these goals.

Comment: While agreeing with the proposed and existing MVP guiding principles, a few commenters had questions about how they would be operationalized. A few commenters supported guiding principle 4. A few commenters questioned how MVPs would help reduce barriers to APM participation and one commenter suggested that we work with specialty societies to develop implementation approaches such as an APM blueprint with guidance for clinicians and further cost measure development. A few commenters voiced a concern that many medical specialties, for example, dermatology, do not have any APMs to work towards.

Response: We appreciate the support for previously finalized guiding principle 4, MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement. Experience with MVPs that measure quality of care and patient experience of care, cost, continuous practice improvement, and effective management and transfers of health information will help to reduce barriers to APM participation (84 FR 40732 through 40733 and 84 FR 62947). We believe that MVPs, which better align cost and quality measurement and use measures meaningful to clinician practice performance, will help clinicians develop skills and processes that increase their readiness for APM participation. This experience with MVPs may stimulate clinician care improvement processes, a growth of data handling infrastructures, and increase clinician understanding of delivery of high value care. That is, MVP experience with cost and quality measurement may help improve clinician readiness to take on financial risk in APMs. This increased clinician understanding of the quality and cost relationship and improvement approaches derived through MVP use may increase clinician confidence and capacity to engage in APMs. We intend to develop MVPs in collaboration with stakeholders that align with the guiding principles. We anticipate these low burden, meaningful MVPs will move clinicians along the value continuum and facilitate movement into APMs by leveraging APM measures where feasible, and linking cost and quality. We acknowledge, that given the number

of Advanced APMs that are now available and the large number of specialty types, some specialists do not currently have an APM they could participate in. New APMs continue to be developed both inside and external to CMS and we envision that the number of APMs will grow in the future. We encourage specialists to collaborate with CMS and within the Health Care Payment Learning Action Network (HCPLAN) to help drive progress towards value-based care. We will continue to engage with stakeholders, including specialty societies, on how MVPs may reduce barriers to APM participation in the future. We are holding a MVP Town Hall meeting on January 7, 2021 (see 85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on MVP topics, including how MVPs can help reduce barriers to APM participation.

Comment: One commenter suggested that in guiding principle 1 the term ''limited'' could be used to define MVPs too narrowly and exclude specialties from being assessed on relevant episodes of care and that we should balance the interests of multiple specialties under each proposed MVP.

Response: The word ''limited'' in this guiding principles means that the number of performance measures and activities in each MVP will be small as compared to, for example, the more than 200 MIPS quality measures a clinician may choose from, we do not use ''limited'' here to constrict the overall number of MVPs as the commenter suggests. While the ''limited'' wording was in our previously finalized guiding principle 1, we proposed adding the words ''connected complementary'' to describe MVP sets of measures and activities that are meaningful to clinicians including specialists. We intend to balance performance measurement standardization with measures that are meaningful to clinicians as we develop MVPs in collaboration with stakeholders.

Comment: A few commenters voiced their support for the concept of subgroup reporting as proposed in guiding principle 2, due to the flexibility it provides to specialists and the more meaningful performance data that results. A few commenters suggested that subgroup reporting be extended to traditional MIPS. A few commenters supported subgroup reporting only if it is optional for multispecialty groups and suggested that incentives be created for subgroup reporting to counter the additional reporting burden. A few commenters expressed interest in the potential of subgroup reporting as related to their specific specialties, which include anesthesiologists, electrophysiologists, endocrinologists, occupational therapists, and otolaryngologists. One commenter provided conditional support of the subgroup reporting concept depending on how a combined final score would be calculated and whether feedback would be provided at the pathway level for subspecialties to be able to receive tailored feedback. One commenter suggested a transition period to incentivize subgroup participation.

Response: We appreciate the support of proposed guiding principle 2. We envision subgroup reporting would be implemented as an option for multispecialty groups reporting MVPs in the future. We did not propose to add a subgroup reporting option to traditional MIPS and believe that the subgroup reporting option within MVPs is sufficient as we expect that eventually the majority of MIPS clinicians will transition to MVP reporting in the future. We have not proposed the details of subgroup reporting, data feedback, scoring or incentives for subgroup reporting but will consider all comments on subgroup reporting as we develop and propose MVP subgroup reporting implementation policies in the future. In terms of a transition period, we intend to implement MVPs incrementally with voluntary participation, which we believe will allow clinicians to transition, as they are ready, into MVP and subgroup reporting.

Comment: Several commenters did not support the concept of subgroup reporting due to concerns related to added program complexity, added burden, and the need for clinicians to compare the scoring advantages of group, subgroup, and individual reporting. One commenter suggested that some specialties may not have a corresponding MVP to report and it may be unrealistic to report performance data on the entire multispecialty group. One commenter suggested that it is possible to develop or identify measures that could result in valuable comparative data comparing a few MVPs but believes that it may be challenging to identify measures that are comparable across all MVPs. One commenter had a concern that a future requirement for subgroup reporting that requires a minimum percent clinician representation would be burdensome and discourage MVP participation. One commenter suggested that testing the attribution methodology for sub-group reporting is critical. One commenter suggested that subgroup reporting would deter team-based care, increase competition, and produce unintended consequences. This commenter suggested that applying Promoting Interoperability requirements to a subgroup rather than a group would discourage MVP selection.

Response: Multispecialty groups, especially groups with many clinicians, often provide an array of services that may not be captured in a single set of measures or in a single MVP. We proposed a modified MVP Guiding Principle 2 as we intend to propose subgroup MVP reporting in the future which would allow clinicians who want to voluntarily report measures that better represent the services they provide to do so. Regarding measure challenges related to comparable measures across all MVPs, within traditional MIPS we require performance measure and activity reporting across four categories (quality, costs, Promoting Interoperability, and improvement activities) and believe there is opportunity to improve comparative data within MVPs as we move in the direction of standardization. We agree with the commenter that it may be challenging to identify measures that are comparable across all MVPs but believe that a future state where clinicians who deliver similar services and report the same MVP will be an improvement over traditional MIPS where wide choices of performance measures and activities, produce challenges in obtaining comparative data. We intend to work with stakeholders to develop MVPs that include meaningful measures and build a portfolio of MVPs that improve comparative data within and across MVPs. We have not proposed implementation details or any minimum criteria for subgroup reporting. We acknowledge that since we plan to incrementally implement MVPs in future years, that some specialties will not initially have a respective MVP. The policies related to operational aspects of subgroup MVP reporting will be developed through future rulemaking with input from stakeholders and we will seek to mitigate concerns such as those voiced by commenters that include complexity, burden, attribution challenges, Promoting Interoperability requirements, unintended consequences, and whether subgroup reporting incentives are warranted. We are holding a MVP Town Hall meeting on January 7, 2021 (see 85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on MVP topics, including subgroup reporting.

Comment: A few commenters suggested that the group reporting option continue to be available. One commenter suggested there could be undue burden on multi-specialty groups when each specialty/clinician reported separately and this resulted in separate payment adjustments, as it would be difficult to keep up with the scoring methodology and payment adjustments and would also create confusion for consumers in determining how well a group is performing.

Response: As we implement MVPs and propose to implement subgroup reporting, we intend to continue the group reporting option. We thank the commenters for their feedback and understand their concerns around reporting, scoring, and payment adjustment. We believe that the statute requires CMS, to the extent feasible, to make group reporting comprehensive. We would balance more comprehensive reporting with concerns about complex reporting and scoring and separate payment adjustments. Though we are considering if, in a future state, it would be feasible to require multispecialty groups to report through subgroups and therefore not report as a single group, we do not believe that it would be feasible in the initial years. We are holding a MVP Town Hall meeting on January 7, 2021 (see 85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on MVP topics, including subgroup reporting.

Comment: One commenter requested that CMS place a cap on the amount of measures that any one TIN would have to report. One commenter stated their belief that it will be difficult for developers and CMS to meet the 2nd guiding principle of providing valuable information to patients and caregivers if the MVP components are not meaningful to patients and caregivers.

Response: We do not believe that the suggested cap on number of measures a TIN must report is necessary as subgroup reporting will be optional for multispecialty groups during the MVP transition years. We intend that MVP components be meaningful to patients and caregivers and refer the commenter to our MVP development criteria finalized in section IV.A.3.a.(2)(a)(i) of this final rule that ensures meaningful MVPs that are comprehensible and understandable.

Comment: One commenter voiced concern related to linking cost and quality measurement in MVPs for specialties that rarely receive attribution in the cost performance category and urged CMS to be transparent in our cost attribution methodology.

Response: Regarding the commenter concern about linkage of specialty cost and quality measurement challenges in MVPs, as referenced in guiding principle 4, we refer the commenter to MVP Development criteria, section IV.A.3.a.(2)(a)(i) where we state that in cases where there are not relevant cost measures for a specific type of care being provided, a broadly applicable cost measure should be considered for MVP inclusion. We are also interested in focused feedback on what additional cost measures should be prioritized for future development and inclusion in the MVP candidate.

Comment: One commenter recommended that CMS revise guiding principle 2 to read: MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care ''and their overall health and well-being.''

Response: We expect the guiding principles to work together to promote our overall goals and we include a meaningful measures principle which looks to improve clinician performance. While MVP comparative data will help patients make clinician selection choices, it is not clear that the comparative data would be available at a level that explicitly helps patients' over-all health and well-being. Therefore, we are not adding the suggested wording to guiding principle 2.

Comment: One commenter encouraged CMS to provide additional guiding principle 2 guidance on how ''sufficient comparative data'' will be ensured, for example, by using single or a limited set of sources to aggregate, analyze and submit data within a given domain.

Response: We proposed to update MVP guiding principle 2 to highlight the importance of more comprehensive multispecialty reporting through subgroups as a step in improving comparative performance data. The movement towards standardization of measures reported within MVPs will improve our ability to ensure comparative clinician performance data. We intend to develop policies related to ensuring comparative data and subgroup reporting with stakeholder input and plan to provide further information related to implementation of this guiding principle in the future. We believe that subgroup reporting allows increased comprehensiveness of multispecialty group performance data as more services can be represented when more than one MVP can be reported.

Comment: Several commenters requested clarifications and details of how subgroups would work operationally. Topics listed for clarification include scoring methodology, subgroup election process, and attribution, and thresholds. One commenter suggested that we mitigate the risk of subgroup payment penalties during transition years. One commenter urged CMS to continue clarifying how MVPs will benefit multispecialty physician practices.

Response: We proposed allowing subgroup reporting as a part of our MVP guiding principles and have not developed or proposed subgroup operational processes. As stated previously in this final rule, we intend to work with stakeholders to develop subgroup reporting policies and processes and intend to make subgroup MVP reporting available in future years. Stakeholder input into scoring, subgroup election processes, attribution, and minimal thresholds (if any) will be considered as we move ahead with subgroup reporting policy proposals in the future. MVPs will benefit multispecialty physician practices in that as more MVPs become available, groups will be able to continue to participate in MIPS via subgroups to more fully reflect the breadth of services provided by the various clinician types within the group. We intend that subgroup reporting will assist in improving the meaning and robustness of the performance data used to incentivize high quality and cost-effective care and providing information that patients can use to select clinicians.

Comment: One commenter seemed to suggest that subgroup reporting was an unnecessary step towards more comprehensive performance data by suggesting that electronic health records can capture individual clinician performances that aggregate into group performance, which they believe many practices have reported to CMS these past few years. The commenter further suggested that instead of changing from group reporting to individual reporting, we should consider a mechanism to collect performance details that obtain individual performances while maintaining group reporting option and scoring. One commenter suggested an alternate to subgroup reporting saying it may be more meaningful to have cross-cutting specialty measures for reporting, and provided an example of diabetes chronic condition care, which involves expertise from ophthalmologists, endocrinologists,

primary care providers, cardiologists and nephrologists.

Response: We intend that subgroup reporting would not be restricted to a single data submission type, for example, EHRs, and would like to leverage current and developing technologies, as indicated by MVP guiding principle 5, to reduce reporting burden as MVPs and subgroup reporting is implemented. We encourage stakeholders to share with us new technologies and opportunities to further our goal of comprehensive and comparative performance data while limiting or reducing clinician MVP reporting burden. Regarding the cross-cutting specialty measures suggestion, we note that our MVP development criteria in section IV.A.3.a.(2)(a)(i) of this final rule, includes an appropriateness element related to whether the MVP is reportable by multiple specialties. Our MVP criteria state that to the extent feasible, specialty and sub-specialty specific quality measures are incorporated into the MVP and that broadly applicable (cross-cutting) quality measures may be incorporated if relevant to the clinicians being measured (refer to section IV.A.3.a.(2)(a)(i) of this final rule). While we appreciate the commenter's interest in cross cutting performance measurement, we do not believe it is an alternative to subgroup reporting, which allows multispecialty groups to voluntarily report on MVPs that have more clinical relevance to various specialties and health priorities.

Comment: One commenter, referring to guiding principle 3, requested clarification of whether each MVP developer will be required to incorporate the patient voice. Another commenter recommended that with appropriate guidance from CMS, and integration of growing patient engagement practices, the inclusion of the patient voice should be mandatory.

Response: We proposed modifying guiding principle 3 to read, MVPs should include measures selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included, to encourage performance improvements in high priority areas. We emphasize in the guiding principle that the patient voice should be captured whenever possible and if not possible, the reason should be clear, for example, if for a certain non-patient facing specialty MVP, there are no relevant patient reported measures currently available. As a part of the MVP development process, we believe that it is important to develop MVPs in a manner that takes into consideration the patient's experience, satisfaction, and outcomes and capturing the patient voice will be used as a criterion as we assess candidate MVPs.

Regarding the commenter recommendation about guiding principle 3 language, ''whenever possible, the patient voice must be included'' and their belief that the patient voice should be mandatory, we refer the commenter to our MVP criteria, incorporation of the patient voice, in section IV.A.3.a.(2)(a)(i) of this final rule and our capturing the patient voice in section IV.A.3.a.(2)(a)(ii) of this final rule which make clear our commitment to inclusion of the patient voice both in our MVP criteria and during MVP development. In addition to including patients as a part of the MVP development process, we encourage stakeholders to utilize several approaches to incorporate the patient perspective, such as using focus groups, in-depth interviews with patients, and informal listening sessions, to the extent feasible, for a comprehensive patient perspective. We have finalized in this rule the expectation of patient voice inclusion in MVP measurement and MVP development.

Comment: A few commenters suggested that we add language to the MVP guiding principles to recognize social determinants of health, with one commenter suggesting that the MVP guiding principles explicitly recognize that healthcare outcomes and cost are shaped by, but go beyond, physicians and the care they provide and are substantially attributable to social factors. One commenter again (85 FR 50280) recommended that we supplement guiding principle 3 by stating explicitly measurement of ''high priority areas of morbidity and mortality.''

Response: We aim to implement MVPs that incentivize high value care and encourage clinicians to make care improvements based on performance measurement data. The Assistant Secretary for Planning and Evaluation (ASPE) Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program explored how the social determinants of health impact clinician performance data and value-based programs.[120] This report was publicly released in June 2020 and builds on the analyses included in an earlier report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs. As we continue to review the analyses and findings of the report, we are considering its recommendations, along with any updated data that would become available, for future rulemaking. We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify longer term policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences. As this work progresses, we will assess whether adding any social determinants of health wording to our MVP guiding principles is appropriate. We note that in support of social factor impacts we are finalizing in section IV.A.3.a.(2)(a)(i) of this final rule the proposed MVP criteria related to MVP developer consideration of patients in rural and underserved areas.

We do not believe it is appropriate to add the recommended ''morbidity and mortality'' wording in guiding principle 3 as we do not want to restrict what we mean by ''high priority areas'' to only morbidity and mortality performance improvements (85 FR 50281); we want to encourage performance improvements in a variety of high priority areas.

Comment: A few commenters requested clarification of a definition of ''digital quality measures'' and the associated criteria for MVP measures. One commenter suggested that while digital measures would reduce burden for some, they would increase burden for others and another commenter suggested equity be considered in the use of eCQMs and digital measures for clinicians. One commenter would like to see digital quality measure exceptions for small practices which are not fully electronic. Another commenter suggested clinician choice in selection of dQMs to report. One commenter suggested that as we implement guiding principle 5, we expand the scope to incentivize building an infrastructure of digital systems that track patients longitudinally, inform care decisions, and support their quality improvement efforts. One commenter requested clarification as to whether our examples of dQMs suggested that eCQMs and MIPS CQMs will eventually be collapsed into a single undifferentiated collection type of dQM and that this could lead to a more optimally hybridized environment of quality measure development, collection and reporting. One commenter suggested that MVP digital measures should include all potential validated data sources, particularly patient reported outcomes and remote patient monitoring data, not just administrative data. One commenter suggested that we

[120] ASPE Second Report to Congress. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

need to better define ''digital'' technologies and the associated measure reporting requirements. One commenter, referring to guiding principle 5, encouraged us to more broadly recognize use of electronic data, such as MIPS credit for wearable devices initiatives. One commenter urged CMS to continue investing in further developing standards that support accurate data quality. A few commenters did not support proposed guiding principle 5 citing EHR, IT and cybersecurity burden concerns for small and rural practices. One commenter requested that we consider MVP development criteria that take into account those clinicians who may not be able to satisfy electronic reporting requirements.

Response: We proposed adding new MVP guiding principle 5, MVPs should support the transition to digital quality measures, to communicate our future vision for reducing MVP reporting burden through leveraging digital innovation. Digital Quality Measures (dQMs) originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems. Examples of digital sources include electronic health records (EHR), health information exchanges (HIEs), clinical registries, case management systems, electronic administrative claims systems, electronically submitted assessment data, and wearable devices. Electronic clinical quality measures or eCQMs (data derived from electronic medical records) are a subset of dQMs (85 FR 50281). As we develop MVPs and incorporate dQMs into MVPs we will consider the operational elements, transitional factors and how movement to dQMs impacts clinician burden, office protocols, cross-MVP equity, and small practices in keeping with our intent to reduce burden. We believe including dQMs in MVPs will incentivize the building of clinician infrastructures of digital systems. We intend to continue supporting the development of dQMs and look forward to inclusion of these measures in MVPs in the future.

After consideration of public comments, we are finalizing our proposals as proposed.

(2) MVP Development

(a) Process of Developing MVPs

In the CY 2020 PFS final rule (84 FR 62948), we finalized at § 414.1305 the definition of a ''MIPS Value Pathway'' to mean a subset of measures and activities established through rulemaking. We also clarified our intention to develop MVPs, to the extent feasible, in collaboration with stakeholders (84 FR 62947). Commenters suggested us to work in tandem with clinicians and specialty societies to develop MVPs (84 FR 62948) and have supported the development of MVPs with robust stakeholder input and feedback opportunities. Stakeholders have also clearly emphasized the need for input during the design and implementation of MVPs. We believe it is important to emphasize that the transition to MVPs must occur gradually, without immediate elimination of the current MIPS program, as we continue to work collaboratively with stakeholders regarding MVP development. As MVPs are developed collaboratively and in a manner that involves dialogs with stakeholders, they must be created utilizing a consistent set of parameters and criteria, to ensure that MVPs are constructed and implemented in a uniform manner. In addition, we believe it is important to outline the methods in which collaboration and engagement may occur with stakeholders. Lastly, we intend on formulating a standardized process in which stakeholders can submit formal MVP candidates for CMS' consideration.

(i) MVP Development Criteria

In response to the RFI in the CY 2020 PFS final rule, we have received stakeholder comments that supported the move to MVPs with considerations to departing from the traditional reporting requirements of the existing MIPS program, such as reporting 6 quality measures for the Quality performance category. We also received stakeholder comments through the RFI that supported the use of electronically available measures such as eCQMs and the use of QCDR measures to the extent feasible. Stakeholders also expressed that it is important that the collection type of quality measures be considered as MVPs are designed. As a part of the MVP development process, consideration should be given to the four performance categories in MIPS, and whether the MVP has a clearly defined intent, offers value, and opportunity for improvement. We believe that as a part of MVP development, it is important to clearly identify linkages between the measures and activities within an MVP which will demonstrate the relevancy of measures and activities to the clinicians being captured within the MVP. Furthermore, as MVPs are developed it is important to factor in the appropriateness of the measures and activities being included and the comprehensibility of the MVP to clinicians and patients. Lastly, considerations must be given to existing criteria for measure and activity inclusion or removal, as established for each of the performance categories. For example, as described in the CY 2019 PFS final rule (83 FR 59763) for the quality performance category, quality measures that are identified as extremely topped out (reaching an average performance rate between 98 to 100 percent) will likely be removed from the program. We refer readers to the CY 2020 PFS final rule (84 FR 62949 through 63006) for discussion of previously finalized measure and activity requirements across the Quality, Cost, Improvement Activity, and Promoting Interoperability performance categories. In addition, we also referred readers to section IV.A.3.c. of the CY 2021 PFS proposed rule for updates to the respective performance categories. Therefore, beginning with the 2022 MIPS performance period, we proposed to develop and select MVPs using the following criteria:

- Utilization of Measures and Activities across Performance Categories.

(a) MVPs should include measures and activities from the Quality, Cost, and Improvement Activities performance categories.

(b) MVPs should include the entire set of Promoting Interoperability (PI) measures.

- Intent of Measurement:

(a) What is the intent of the MVP?

(b) Is the intent of the MVP the same at the individual clinician and group level?

(c) Are there opportunities to improve the quality of care and value in the area being measured?

(d) Why is the topic of measurement meaningful to clinicians?

(e) Does the MVP act as a vehicle to incrementally phase clinicians into APMs? How so?

(f) Is the MVP reportable by small and rural practices? Does the MVP consider reporting burden to those small and rural practices?

(g) Which Meaningful Measure Domain(s) does the MVP address?

- Measure and Activity Linkages with the MVP:

(a) How do the measures and activities within the proposed MVP link to one another? (For example, do the measures and activities assess different dimensions of care provided by the clinician?)

(b) Are the measures and activities related or a part of the care cycle or continuum of care offered by the clinicians?

(c) Why are the measures and activities most meaningful to the specialty?

• Appropriateness:

(a) Is the MVP reportable by multiple specialties? If so, has the MVP been developed collaboratively across specialties?

(b) Are the measures clinically appropriate for the clinicians being measured?

(c) Do the measures capture a clinically definable population of clinicians and patients?

(d) Do the measures capture the care settings of the clinicians being measured?

(e) Prior to incorporating a measure in an MVP, is the measure specification evaluated, to ensure that the measure is inclusive of the specialty or sub-specialty?

• Comprehensibility:

(a) Is the MVP comprehensive and understandable by the clinician or group?

(b) Is the MVP comprehensive and understandable by patients?

• Incorporation of the Patient Voice:

(a) Does the MVP take into consideration the patient voice? How?

(b) Does the MVP take into consideration patients in rural and underserved areas?

(c) How are patients involved in the MVP development process?

(d) To the extent feasible, does the MVP include patient-reported outcome measures, patient experience measures, and/or patient satisfaction measures?

• Measures and Improvement Activities Considerations: MIPS Quality Measures.

We were not prescriptive on the number of quality measures that are included in an MVP. In selecting quality measures, we stated that we believe that consideration should be given to the following:

(a) Do the quality measures included in the MVP meet the existing quality measure inclusion criteria? *(For example, does the measure demonstrate a performance gap?)*

(b) Have the quality measure denominators been evaluated to ensure the eligible population is consistent across the measures and activities within the MVP?

(c) Have the quality measure numerators been assessed to ensure the measure is applicable to the MVP topic?

(d) To the extent feasible, does the MVP include outcome measures, or high priority measures in instances where outcome measures are not available or applicable? We encourage stakeholders to utilize our established pre-rulemaking processes, such as the Call for Measures, described in the CY 2020 PFS final rule (84 FR 62953 through 62955) to develop outcome measures relevant to their specialty if outcome measures currently do not exist and for eventual inclusion into an MVP.

(e) To the extent feasible, does the MVP include electronically specified clinical quality measures?

(f) To the extent feasible, does the MVP avoid including quality measures that are topped out?

(g) What collection types are the measures available through?

(h) What role does each quality measure play in driving quality care and improving value within the MVP? Provide a rationale as to why each quality measure was selected.

(i) How do the selected quality measures relate to other measures and activities in the other performance categories?

(j) To the extent feasible, specialty and sub-specialty specific quality measures are incorporated into the MVP. Broadly applicable (cross-cutting) quality measures may be incorporated if relevant to the clinicians being measured.

• Measures and Improvement Activities Considerations: Cost Measures.

(a) What role does the cost measure(s) play in driving quality care and improving value within the MVP? Provide a rationale as to why each cost measure was selected.

(b) How does the selected cost measure(s) relate to other measures and activities in other performance categories?

(c) If there are not relevant cost measures for specific types of care being provided (for example, conditions or procedures), does the MVP include broadly applicable cost measures (that are applicable to the type of clinician)?

(d) What additional cost measures should be prioritized for future development and inclusion in the MVP?

• Measures and Improvement Activities Considerations: Improvement Activities.

(a) What role does the improvement activity play in driving quality care and improving value within the MVP? Provide a rationale as to why each improvement activity was included.

(b) Describe how the improvement activity can be used to improve the quality of performance in clinical practices for those clinicians who would report this MVP.

(c) Does the improvement activity complement and/or supplement the quality action of the measures in the MVP, rather than duplicate it?

(d) To the extent feasible, does the MVP include improvement activities that can be conducted using CEHRT functions? The use of improvement activities that specify the use of certified health IT will help to further align with the CEHRT requirement under the Promoting Interoperability performance category.

(e) If there are not relevant specialty or sub-specialty specific improvement activities, does the MVP includes broadly applicable improvement activities (that is applicable to the clinician type) are used?

• Measures and Improvement Activities Considerations: Promoting Interoperability (PI) Measures.

(a) Must include the full set of PI measures.

The MVP development criteria was developed primarily with consideration with the MVP guiding principles, discussed above. In addition, we considered the spectrum of measures and activities available for MVP development, and the criteria used to include measures and activities within each of the respective performance categories. Through the collaborative process of co-developing MVPs with stakeholders, we have realized how crucial it is to establish a set of MVP development criteria that would standardize what is expected of MVPs and provide our evaluation criteria in a transparent manner. We stated that we believe that the aforementioned criteria will lead to the development of MVPs in a manner that is consistent and reliable. We sought comment on the MVP development criteria.

We received public comments on the MVP development criteria proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters broadly supported the MVP criteria.

Response: We agree and thank the commenters for their support on the MVP criteria. We believe that the establishment of MVP development criteria will allow stakeholders to better understand of our vision for MVPs and ensure that MVPs are constructed in a consistent manner.

Comment: Several commenters broadly supported the MVP criteria. One commenter suggested CMS to continue to prioritize interoperability as a foundational requirement in the new MVP Program. One commenter agreed that MVPs should include criteria related to utilization, intent, and linkage of measures because this would help develop new MVPs. One commenter suggested CMS provide flexibility for innovative MVPs.

Response: We thank the commenters for their support on the MVP criteria,

we believe there is importance to establishing criteria in which MVPs will be developed and implemented for consistency purposes. We also agree that interoperability is an important priority, and should therefore, be included in MVPs as a foundational requirement. We also agree that criteria related to utilization, intent, and linkages would assist in the development of MVPs. Lastly, we continue to encourage stakeholders to be innovative as they partake in MVP development and collaboration with CMS while aligning with the MVP development criteria as described. We do not believe additional flexibility beyond what is described in the MVP development criteria is needed, as we emphasize that MVPs should be developed utilizing a standardized framework.

Comment: Commenters expressed that MVPs should be tailored for participating clinician specialists', such as anesthesiologists, neurosurgeons, rehabilitation medicine, occupational therapists, physical therapists, and speech-language pathologists. A few commenters stated that MVPs should be collaboratively developed by specialties before submission to CMS. One commenter expressed that MVPs could be considered condition-specific (when specialists are part of a larger core team) or specialty-specific (when specialists are treating patients with a wide range of diagnoses). One commenter expressed that specialty organizations would have difficulty contributing measures to MVPs that are not specialty specific.

Response: We agree that MVPs should be developed around specialties that participate in the MIPS program to offer clinicians a more meaningful method of reporting. We also strongly agree and would encourage that MVPs should be collaboratively developed amongst specialties, in instances where an MVP covers an episode of care that involves multiple clinician types, such as surgeons and anesthesiologists. Furthermore, we agree that MVPs could be condition-specific or specialty-specific; it will depend on the clinical topic being measured and envision the specialty organizations would suggest specialty specific measures for MVPs over broadly applicable measures. While broadly applicable measures, such as closing the referral loop, can be considered for inclusion in an MVP, because they cover quality actions that are a part of the care continuum, these are not required to be included should more meaningful and relevant specialty specific measures exist. We believe the measures included in an MVP should be relevant and meaningful to the clinical practice of the specialties being measured. We are open to considering candidate MVPs that are created utilizing the MVP development criteria, for specialties including physical and occupational therapy.

Comment: Several commenters expressed that the proposed MVP criteria should include other elements such as the number of measures and activities required. A few commenters recommended CMS work collaboratively with MVP developers and one commenter specified that CMS's MVP approval process should be transparent with the MVP developers so that specialty societies do not invest resources without assurances of success.

Response: As described in the CY 2021 PFS proposed rule (85 FR 50282), we are not prescriptive on the number of measures or activities included in MVPs. We emphasize that the measure and activities should be relevant and meaningful to the topic being measured through the MVP. We intend to provide educational material including plans to host a public facing webinar to help stakeholders better understand and be prepared to implement the MVP development criteria. In addition, we emphasize it is our intention to work collaboratively by having dialogs with stakeholders to develop MVPs that are meaningful and relevant to their given clinical specialties. Lastly, while we intend to continue to work with stakeholders in an iterative manner that fosters transparency, CMS will ultimately determine if and when an MVP candidate is ready for implementation. We intend to follow our normal processes of notice and comment rulemaking to make stakeholders and the public aware of which MVPs we believe are ready for implementation for the upcoming performance period.

Comment: One commenter recommended CMS clearly define a pathway to phase clinicians into APMs.

Response: We intend that MVPs will assist clinicians and practices as they prepare to take on and manage financial risk, as in Advanced APMs, as they build out their quality infrastructures that align with the MIPS performance categories and gain experience with cost measurement. We believe that experience with MVPs, in which there is aligned measurement of quality (of care and of experience of care) and cost, continuous improvement/innovation within the practice, and efficient management and transfers of information, will help remove barriers to APM participation.

We refer readers to the infographic at *https://qpp.cms.gov/mips/mips-value-pathways*, which provides an overview of our vision for the MIPS path to value future state (see 85 FR 50279). We believe that MVPs, which better align cost and quality measurement and use measures meaningful to clinician practice performance, will help clinicians develop skills and processes that increase their readiness for APM participation. This experience with MVPs may stimulate clinician care improvement processes, a growth of data handling infrastructures, and increase clinician understanding of delivery of high value care. We believe another example of how MVPs may provide a pathway to phase clinicians into APMs may be to consider the inclusion of quality measures in MVPs, which are used in APMs such as the new APM Performance Pathway (APP). The familiarity of reporting those measures, may lead to a smoother glide path for clinicians into APMs.

Furthermore, MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement. Experience with MVPs that measure quality of care and patient experience of care, cost, continuous practice improvement, and effective management and transfers of health information will help to reduce barriers to APM participation (84 FR 40732 through 40733 and 84 FR 62947). We anticipate these low burden, meaningful MVPs will move clinicians along the value continuum and facilitate movement into APMs by leveraging APM measures where feasible, and linking cost and quality. We will continue to engage with stakeholders on how MVPs may reduce barriers to APM participation in the future. We are holding a MVP Town Hall meeting on January 7, 2021 that will provide stakeholders with an opportunity to provide feedback on MVP topics, including how MVPs can help reduce barriers to APM participation. (See the November 23, 2020 **Federal Register** (85 FR 74729 through 74730) for additional information on the January 7, 2021 meeting.)

Comment: One commenter requested that CMS define an MVP governance structure that would include a central point of contact and responsibility to prevent the removal of a measure or an improvement activity that would negatively affect stakeholders and specialties.

Response: All MVPs are subject to notice and comment rulemaking with regards to the proposal of new MVPs,

changes to existing MVPs (in the future), and removal of MVPs or components of an MVP (such as a quality measure or improvement activity). CMS is the central point of contact with regards to MVPs. If there are potential changes to an established MVP, we will consider the potential impacts on all stakeholders prior to proposing the changes. Stakeholders will be able to provide comments on the proposed changes through the public comment period for CMS to consider prior to finalizing the MVPs or changes to the MVPs.

Comment: One commenter requested that CMS clarify if it would withhold MVP approval for a specialty specific MVP if patient reported outcome measures for the specialty specific MVP are not available.

Response: While it is our preference to include outcome and patient reported outcome measures in MVPs, we have stated we would do so to the extent feasible, as we understand that there may be limited availability of patient reported outcome measures for all specialties. Therefore, we encourage the use of other measures that consider the patient voice in MVPs, such as patient surveys, patient satisfaction, or patient experience measures in the interim. It is our vision that MVPs will be made up of a majority of outcome measures and will include a patient reported outcome measure that would represent the patient voice. We continue to encourage stakeholders to use their innovative means to develop and submit through our established pre-rulemakings processes patient reported outcome measures that are meaningful to their specialties, and consider the incorporation of tools such as the PROMIS tool into their measure development.

Comment: One commenter requested that CMS clarify how MVPs will incorporate new technology, such as FHIR (Fast Healthcare Interoperability Resource), into data collection.

Response: As mentioned in the previous section of this final rule, within our MVP guiding principles, we indicate that MVPs should support the transition to digital measures to the extent feasible. The inclusion of digital measures within MVPs may facilitate future use of new technologies such as FHIR, in an effort to provide reporting options that reduce reporting burden for clinicians and groups.

Comment: A few commenters opposed including the full set of promoting interoperability (PI) measures in MVPs and recommended CMS emphasize that improvement activities must utilize certified electronic health record technology (CEHRT). One commenter noted that hospitalists or clinicians who do not interact with patients would not be able to collect and report PI data and that MVPs should be designed to reflect this at the outset by allowing groups to attest to using CEHRT. One commenter suggested CMS maintain the existing PI hardship exceptions as a proxy for the PI measurement requirement.

Response: We believe that interoperability is a foundational element of MVPs. In the CY 2020 PFS final rule (84 FR 62948) we stated that we envision an initial uniform set of Promoting Interoperability measures in each MVP and will consider customizing MVP Promoting Interoperability measures in future years. We believe that eligible clinicians could benefit from more targeted approaches that assess the meaningful use of health IT in alignment with clinically relevant MVPs. As we gain additional years of experience with MVPs, we may be able to consider MVP Promoting Interoperability measures in each MVP, but we want to spend some time assessing what criteria should be used in determining which Promoting Interoperability measures fit or do not fit within a given MVP and why. Furthermore, we agree that the establishment and inclusion of improvement activities (IAs) that require the utilization of certified health IT in MVPs would create a stronger linkage between the PI and IA performance categories. Lastly, the existing bases for reweighting the PI performance category under traditional MIPS also will be available through MVPs.

Comment: A few commenters expressed that many small and rural practices cannot afford implementing electronic health records (EHRs), including the information technology and cybersecurity staff required to maintain EHR security and recommended CMS maintain the Promoting Interoperability performance category small practice hardship exception.

Response: We understand that there may be some barriers for small and rural practices in implementing CEHRT, and do intend on maintaining the hardship exception for small practices as we establish the MVP reporting option. In addition, we intend on applying the existing Promoting Interoperability performance category reweighting policies under § 414.1380(c)(2) as we establish MVPs, with any revisions addressed through future notice and comment rulemaking.

Comment: Several commenters suggested overall measure requirements regarding the number of measures and requested measure clarification. A few commenters requested that MVPs include a limited number of measures. One commenter suggested that clinicians report six quality measures and one outcome measure or high-priority measure. One commenter suggested that specialties and sub-specialties with less than six quality measures should be required to report on all cross-cutting measures.

Response: As mentioned in the CY 2021 PFS proposed rule (85 FR 50282), to date, we have not been prescriptive on the number of quality measures that are included in a given MVP. The measures that are being considered for inclusion of the MVP should meet the standards of the MIPS quality measures and QCDR measures inclusion criteria. Measures incorporated into an MVP should be clinically relevant to the topic being measured. Through the gradual transition to MVPs, we intend on allowing for clinicians to report on smaller but more meaningful sets of measures and activities. We appreciate the feedback regarding MVP reporting requirements, and encourage stakeholders to participate in our MVP Town Hall meeting to provide additional feedback with regards to the number of measures clinicians should be required to report in an MVP. As noted previously in this section, we are holding a MVP Town Hall meeting on January 7, 2021 (85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on this amongst other MVP topics. We thank the commenters on their suggestions in regards to reporting requirements for specialties and sub-specialties with less than six quality measures, and will take the comment into consideration for future rulemaking.

Comment: One commenter requested clarification on whether every MVP measure and improvement activity should have the same denominator.

Response: To clarify, every measure and improvement activity does not have to have the same denominator. However, we encourage stakeholders to consider the denominator eligible population across the measures being considered for inclusion in the quality and cost component of the MVP. In addition, we also encourage stakeholders to review the measure specifications to validate that the places of service they would like reflected within the MVP, for example, inpatient or outpatient are included. We encourage this review, so that stakeholders are cognizant of incorporating measures that are widely

applicable to the clinicians they intend to measure through the MVP. Furthermore, improvement activities do not utilize numerators and denominators like measures do. Therefore, we encourage stakeholders to utilize improvement activities that are complementary to the quality actions captured by the quality measures and cost measures included within the MVP candidate.

Comment: One commenter stated CMS should ensure there are enough measures to create MVPs applicable for the more than 1 million eligible clinicians that currently participate in the MIPS program, specifically specialists.

Response: In the MIPS program, we have implemented two inventories of measures, which include MIPS quality measures that are submitted through the Call for Measures following the pre-rulemaking process that are eventually proposed and finalized through notice and comment rulemaking. The other inventory of available measures are developed by CMS approved Qualified Clinical Data Registries (QCDRs). We refer readers to the Quality Payment Program (QPP) resource library: *https://qpp.cms.gov/about/resource-library* for details on the available inventories of quality measures and QCDR measures for the 2020 performance period. The measure inventories for the 2021 MIPS performance period will be posted to the prior to the start of the performance period in the QPP resource library. We believe the existing inventories of measures are enough to start creating applicable MVP candidates. Moreover, we continue to encourage measure stewards and QCDRs to innovatively develop measures and keep in mind our desire to transition our inventory of measures to be largely based on outcome measures and develop measures that are outcome, intermediate outcome, or patient reported outcome based.

Comment: Another commenter recommended allowing specialties to rapidly test and replace obsolete measures.

Response: We agree and highly encourage stakeholders, such as specialty groups and measure developers to participate in measure development and submit measures through the Call for Measures as soon as possible to replace retired measures with measures that are more robust and outcomes based. In following the pre-rulemaking guidelines to ensure their measures can be considered, the process also includes measure testing amongst other requirements. We refer readers to the pre-rulemaking website for a comprehensive list of measure development requirements and resources at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Pre-Rulemaking-MUC.*

Comment: Commenters recommended that CMS incorporate patient-reported outcomes measures (PROMs) into MVPs and expressed that these measures not only improve the quality of care but also help patients make more informed decisions. Commenters also recommended that PRO tools such as PROMIS, SDM–Q–9, and CollaboRATE be incorporated into the MVP quality score.

Response: We agree with the commenters that patient reported outcome measures provide value and improve the quality of care, and to the extent feasible, should be included in MVPs. We also agree that PRO tools are valuable, but need to be incorporated into a measure or activity in order to contribute to the MVP quality score per statutory requirements.

Comment: One commenter requested CMS to clarify the number of MVPs per specialty and a few commenters recommended sub-specialty MVPs. For example, one commenter recommended CMS support the development of multiple surgical and procedural MVPs to represent anesthesia practice settings to provide sufficient MVP choices for ECs and groups.

Response: To date we have not been specific as to the maximum number of MVPs a given specialty should have. We are cognizant of the potential need for MVPs that are sub specialized and that the number of MVPs available per specialty may vary. We believe discussions with the specialties will help to determine the best path forward, while keeping in mind our desire to avoid creating large volumes of MVPs per specialty, which may create more complexity and may lead to overwhelmed clinicians unsure of which MVP to report. After consideration of the public comments received, we are finalizing our proposals as proposed.

(ii) Capturing the Patient Voice

As a part of the MVP development process, we believe that it is important to develop MVPs in a manner that takes into consideration the patient's experience, satisfaction, and outcomes. We believe that MVPs should be constructed in a manner that should not only be understood by clinicians, but by patients who may use the ascertained information to make informed decisions regarding their health care providers. Therefore, beginning with the 2022 performance period, we proposed that stakeholders that are developing MVPs to submit to CMS as candidate MVPs should include patients as a part of the MVP development process. We stated that stakeholders should incorporate patients and/or patient representatives through means that may include, but are not limited to technical expert panels or an advisory committee as they work to construct their candidate MVPs prior to reaching out to CMS with a candidate submission. The process of involving patients as a part of the stakeholder's MVP development would be considered a pre-requisite for CMS to consider the candidate MVP for the upcoming performance period. By including patients and/or patient representatives in the MVP development process, we stated we believe that patients will be able to voice how to make the outcomes of measurement meaningful to them. In addition to including patients as a part of the MVP development process, we encouraged stakeholders to utilize several approaches to incorporate the patient perspective, such as using focus groups, in-depth interviews with patients, and informal listening sessions, to the extent feasible, for a comprehensive patient perspective. We sought comments on the proposal.

We received public comments on the capturing the patient voice proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the inclusion of the patient voice in the MVP development process.

Response: We thank the commenters for their support, and agree that there is importance in including the patient voice in the MVP development process. We believe that including patients as a part of the MVP development process will allow for the development of MVPs that provide data that is meaningful to patients as they select providers.

Comment: One commenter opposed the addition of MVP development criteria, citing concern that these will delay MVP development. The commenter suggests that CMS subject each MVP candidate to a robust screening process that includes patient perspective, rather than putting the onus on developers to do so.

Response: We disagree that the establishment of MVP development criteria will delay MVP development. We believe that the creation of MVP development criteria will allow for the implementation of MVPs that are created in a consistent manner that aligns with our vision of MIPS Value Pathways moving clinicians to more meaningful measurement that creates

betters opportunities for quality improvement. Furthermore, we disagree with the commenter's suggestion that CMS alone subject each MVP candidate to a screening process that includes patients. We believe that stakeholders who choose to create a MVP candidate around a clinical topic should consider the patient perspective as a part of the development process rather than waiting until the candidate MVP has completed development to obtain patient feedback. The consideration of the patient perspective in the midst of the development process allows stakeholders to consider the feedback and make changes to their development process that will help to result in a better quality MVP candidate.

Comment: A few commenters recommended that CMS delay implementing the criteria that the MVP is comprehensive and understandable by patients. A few commenters requested a delay until the 2023 performance year so that a technical expert panel could be convened.

Response: We disagree that this criteria should be delayed until the 2023 performance period. We believe all MVP candidates need to be developed with this criteria in mind to ensure that the data collected from MVPs are meaningful for patients to make informed decisions regarding their patient care. Furthermore, it is not a requirement that stakeholders convene technical expert panels, therefore, we disagree that there be a delay until the 2023 performance period. While we have established criteria to develop MVPs, it is to the discretion of the stakeholder to determine how elaborate of a development process they would like to undertake and when their MVP candidate is ready for CMS review and consideration.

Comment: Several commenters recommended approaches for CMS to engage patients. One commenter expressed concern about how CMS will evaluate patient engagement during the MVP development process.

Response: We thank the commenters for their recommendations; however, we note that the requirement is for stakeholders who wish to submit an MVP candidate to CMS. Those stakeholders must engage with patients as a part of their MVP development process prior to submitting the MVP candidate for CMS review and consideration. While we are not prescriptive that patient engagement occur using a single approach, we plan to recommend stakeholders to describe how they engaged patients in the MVP development process through the MVP candidate submission template to help us understand how the patient's perspective was considered in the development process.

Comment: One commenter requested that CMS make exceptions for the inclusion of patient representatives in MVP development in cases where organizations are able to demonstrate that patient reported outcomes cannot be used. Another commenter requested clarity on whether each contributor or specialist to an MVP must include patient testing or interviews. The commenter also requested detail on how CMS will verify the inclusion of the patient voice.

Response: We disagree with the commenter request that we make exceptions for the inclusion of patient representatives in the MVP development process in instances where organizations are unable to utilize patient reported outcome measures. We want to clarify that the requirements around the patient voice are complimentary. We are looking for stakeholders to involve patients or patient representatives as a part of the MVP development process, to ensure that patients are able to understand what the MVP is trying to measure. In addition, to the extent feasible, we suggested that patient reported outcome measures be included in MVPs. While it is our preference to include patient reported outcome measures in MVPs, we understand that there may be limited availability of patient reported outcome measures for all specialties. Therefore, we encourage the use of other measures that consider the patient in MVPs, such as patient surveys, patient satisfaction, patient experience, or patient safety measures. We continue to encourage stakeholders to use their innovative means to develop and submit through our established pre-rulemakings processes patient reported outcome measures that are meaningful to their specialties, and consider the incorporation of tools such as the PROMIS tool into their measure development.

Comment: One commenter recommended that CMS develop patient-facing materials describing MVPs and requested that CMS lead education of patient groups on the goals and quality measurement of the MVP.

Response: We thank the commenter for their recommendation. As a part of our education and outreach efforts we intend on developing educational materials and hosting webinars that are meaningful to all stakeholders, including patients. However, we also believe that stakeholders who choose to partake in MVP development should also educate and involve patients regarding quality care in a given area of clinical care improvement.

Comment: One commenter requested CMS to provide equal focus on patient outcomes as patient experience and satisfaction. Another commenter stated that treating and reversing certain chronic conditions and achieving optimal health outcomes. One commenter recommended that MVPs include the Hospital-Wide 30-day All Cause Unplanned Readmission (HWR) Rate measure.

Response: We agree and continue to emphasize our focus on outcomes, including patient reported outcomes, and our desire to move away from process measures. We also agree that attaining optimal health outcomes by treating, managing, and possibly overcoming chronic conditions should be captured in a future MVP. Furthermore, we agree that there is importance in including population health measures in the foundational layer of all MVPs as described below, and we do intend on finalizing the inclusion of the Hospital-Wide 30-day All Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups measure.

After consideration of the public comments, we are finalizing our proposals as proposed.

(iii) Candidate MVP Co-Development, Solicitation Process, and Evaluation

Through the Request for Information (RFI) on transforming MIPS in the CY 2020 PFS final rule we have learned of stakeholders interests in participating in the MVP development process. In summer 2019, we held numerous focus groups with front-line clinicians, specialty societies, advocacy groups, QCDRs, registries, and health IT vendors to listen to what stakeholders were looking for in regards to program simplification, burden reduction, and the intent of MVPs. In response to the CY 2020 PFS final rule, we received several requests from stakeholders who wanted to discuss their perspectives on MVPs and in some cases, walk us through potential MVP candidates from their specialty. Based on continuous stakeholder interest, we believe that a process must be implemented to ensure that stakeholder engagement and collaboration in the development of MVPs is consistent from an overall perspective.

To consider MVP candidates developed by stakeholders, we believe it is important to implement a streamlined approach to receive and evaluate potential MVPs. Therefore, beginning

with the 2022 performance period, we proposed that stakeholders should formally submit their MVP candidates utilizing a standardized template, which will be published in the QPP resource library for our consideration for future implementation. Stakeholders should submit all information including a description of how their MVP abides by the MVP development criteria as described in the CY 2021 PFS proposed rule (85 FR 50281 through 50283), and provide rationales as to why specific measures and activities were chosen to construct the MVP. We believe the utilization of a standardized template would help stakeholders understand what information is needed to evaluate the feasibility of the candidate MVP.

On an annual basis, we intend on hosting a public facing MVP development webinar, to remind stakeholders of MVP development criteria, the timeline, and process in which to submit a candidate MVP. While we believe that engagement with stakeholders regarding MVP candidates may occur on a rolling basis throughout the year, at CMS' discretion we will determine if an MVP is ready for inclusion in the upcoming performance period. As MVP candidates are received, they will be reviewed, vetted, and evaluated by CMS and our contractors. We intend on utilizing the MVP development criteria (discussed above) to determine if the candidate MVP is feasible. In addition to the MVP development criteria listed above, we will also vet the quality and cost measures from a technical perspective to validate that the coding in the quality measures and cost measure(s) include the clinician type being measured, and whether all potential specialty specific quality measures or cost measures were considered, with the most appropriate included. We may reach out to the stakeholder on an as-needed basis, should questions arise as we review. In addition, once we complete our internal evaluation, we will reach out to select stakeholders whose candidate MVP may be feasible for the upcoming performance period, to schedule a feedback loop meeting to have a dialog regarding our feedback, and next steps that may include recommended modifications to the MVP candidate. Since MVPs must be established through rulemaking, as described at § 414.1305, CMS will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the proposed rule. We sought comment on the proposed process to solicit MVP candidates.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the use of an MVP candidate template with one believing it is as a way to reduce administrative burden. Another commenter requested that we release the MVP candidate template far in advance of MVP implementation.

Response: We plan to release the MVP candidate template as soon as possible, and potentially in coordination with the publication of this final rule so it can be immediately available for use by stakeholders.

Comment: One commenter voiced their appreciation for our MVP development discussions and feedback to date and supported the idea of a feedback loop on submitted MVPs and greater transparency in the process.

Response: We thank the commenter for their support; we believe establishing a feedback loop with stakeholders will help to strengthen communications regarding MVP candidates that may be iteratively revised based on our review. While we intend to continue to work with stakeholders in an iterative manner that fosters transparency, CMS will ultimately determine if and when an MVP candidate is ready for implementation. We intend to follow our normal processes of notice and comment rulemaking to make stakeholders and the public aware of which MVPs we believe are ready for implementation for the upcoming performance period. If there are potential changes to an established MVP, we will consider the potential impacts on all stakeholders prior to proposing the changes. Stakeholders will be able to provide comments on the proposed changes through the public comment period for CMS to consider prior to finalizing the MVPs or changes to the MVPs.

Comment: A few commenters objected to the idea that CMS would not communicate to the stakeholder developing a candidate MVP whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the annual QPP proposed rule. A few commenters suggested an interactive dialogue between the stakeholder who has submitted the candidate MVP and CMS would be helpful throughout the development process. One commenter suggested that CMS should provide feedback regardless of whether the MVP will be proposed for implementation and another requested feedback be provided throughout the MVP development process. One commenter believes a clear process and timeline for approving MVPs and new measures should be clearly delineated prior to implementation.

Response: We agree that a dialog between the stakeholder who has developed the candidate MVP and CMS would be meaningful, to ensure that the MVP aligns with program goals and MVP criteria and that CMS provides meaningful feedback on how an MVP may be revised to better align with the aforementioned criteria before being considered for implementation. In some instances, discussions regarding a given MVP candidate may be iterative, and may call for a few meetings to discuss changes. Some MVP candidates may be identified as ready for implementation in the upcoming year, while others may require additional work. That is the reason why we would review MVPs on a rolling basis. In instances where an MVP may not be ready for implementation in the upcoming performance period, it may be ready by the following performance period. The timing in which an MVP may be ready for implementation will be dependent of the MVP's readiness and ability to meet the aforementioned MVP criteria. New measures will need to follow the existing pre-rulemaking processes or QCDR measure requirements to be considered for inclusion in an MVP. While we intend to continue to work with stakeholders in an iterative manner that fosters transparency, CMS will ultimately determine if and when an MVP candidate is ready for implementation. We intend to follow our normal processes of notice and comment rulemaking to make stakeholders and the public aware of which MVPs we believe are ready for implementation for the upcoming performance period.

Comment: A few commenters requested more guidance around expectations, MVP candidate assessment processes and communications. One commenter requested CMS publish MVP development status updates while another commenter requested a CMS website that would provide information on MVPs under development and CMS' initial assessment data.

Response: We intend on hosting a MVP development webinar that will provide additional clarity on expectations, the assessment process and communications between CMS and stakeholders who develop candidate MVPs. We thank stakeholders for their recommendations of how we can make the MVP development process more

transparent, and will take these suggestions under consideration for future implementation, as operationally feasible.

After consideration of the public comments, we are finalizing our proposals as proposed.

(b) Implementing Meaningful Measures in MVPs

(i) Incorporating Population Health Measures Into MVPs

In the CY 2020 PFS proposed rule (84 FR 40742 through 40743), we expressed our interest in incorporating population health measures calculated from administrative claims-based data as a part of the foundational layer within MVPs, in an effort to improve patient outcomes, reduce reporting burden and costs, better align clinician quality improvement efforts, and increase alignment with APMs and other payer performance measurement. Through the RFI, stakeholders expressed concerns with including population health measures due to concerns with reliability, validity, attribution, unintended consequences and/or risk adjustment of claims-based population health measures. We understand stakeholder concerns around the population health measures that were previously considered, and are looking into ways to address and mitigate those concerns. We also received some support from stakeholders who agreed that population health measures will reduce administrative burden with the belief that these measures are not any less relevant to specialists. In MIPS, we currently have one administrative-claims based measure, the All-cause Hospital Readmission measure, which is calculated and scored for groups with 16 or more clinicians that meet a 200-patient case minimum, as described in the CY 2017 Quality Payment Program final rule (81 FR 77300). As described in Appendix 1 of the CY 2021 PFS proposed rule, we proposed to replace the All-cause Hospital Readmission measure with a Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups because the re-specified measure promotes a system level approach by clinicians, with a focus on high risk conditions such as COPD and heart failure. We referred readers to Appendix 1 of the proposed rule for detailed discussion of the newly proposed measure.

The following is a summary of the comments we received and our responses.

Comment: A few commenters support the use of population health measures in MVPs that are relevant to the population and clinical discipline and focus on preventive measures and early detection.

Response: We thank the commenters for their support, and agree that population health measures should be relevant to the population and the clinical topic being measured. We encourage stakeholders to utilize our pre-rulemaking processes to develop additional clinically relevant population health measures. We also agree that prevention and early detection are two areas where population health measures can be focused on.

Comment: Several commenters voiced their opposition to use of population health administrative claims-based measures in MVPs with some listing concerns about the applicability of MVP population health measures to physician groups or specialists, such as anesthesiologists, pathologists and ophthalmologists. A few commenters suggest that population health measures are not actionable with one commenter listing an example of the hospital-wide readmission measure as not actionable for surgeons. One commenter expressed that MVPs should include measures that are meaningful to group practices and their clinicians rather than administrative claims or population health measures, listing the following concerns: Attribution; retrospective analysis; inability to measure individual physicians; and reliability. A few commenters voiced a concern about performance comparison inequities in applying population health measures across different specialties. One commenter provided an alternative to population health measures that require a large sample that we work with specialty societies to explore ''better'' ways to tie claims data to more robust clinical data collected by registries.

Response: We disagree with commenters who oppose the use of population health administrative claims-based measures in MVPs. Measures such as MIPS hospital wide readmission (HWR) should be used within MVPs. The HWR measure is not a traditional population health measure but is designed to incentivize shared responsibility for clinical outcomes.

This measure is a re-specification of the All-Cause Readmission (ACR) measure currently within the MIPS program, which attributes outcomes solely to the primary care physician that provides the plurality of care during the measurement period, regardless of whether this care was provided before, during or after the inpatient stay. The primary care physician may not be the only clinician with opportunity to impact readmissions. The intent of this measure is to improve upon the attribution of the current ACR measure and incentivize collaboration of care across inpatient and outpatient settings by considering shared attribution to up to three eligible clinician groups that provide care for patients inside and outside of the hospital, and therefore are in position to influence patient risk of readmission.

Our contractor convened a Technical Expert Panel (TEP) to seek detailed input from clinicians and patients to attribute the unplanned 30-day readmission outcome to multiple clinicians with the ability to impact readmission risk through their care and communication. The TEP and clinical consultants, most of whom are clinicians themselves and include representatives from anesthesia and surgery, strongly supported the attribution model. They identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions and with ability to influence readmission risk.

As such, we disagree with the commenter that the HWR measure is not actionable for these clinicians. Specifically, the primary inpatient clinician is responsible for the medical care provided during the admission, referring patients to inpatient specialists and prescribing medications; the delivery of their care during the hospital admission can influence whether the patient returns with unresolved medical issues or side effects from inappropriate medication or dosage. The discharge clinician is responsible for preparing the patient for discharge, including determining the patient is well enough to leave the hospital, understands their condition and treatments, and has been referred to outpatient specialists or therapy, as needed. Providing clear instructions and arrangements help ensure that the patient adheres to care, medication, and lifestyle changes outside of the hospital (Bowles et al, 2014, Philips et al, 2004, DeCaporale-Ryan et al, 2017, and Verhaegh et al, 2014). The primary outpatient clinician is responsible for the care of the patient outside of the hospital and can prevent readmissions by ensuring accessibility to care and availability for consultations within 30 days after discharge. Through their individual roles and together through coordinated care, these clinicians can reduce the risk of readmission.

NQF panel and committee members have voted on this measure several times, all of which concluded in favor of endorsing the measure. Final endorsement of the measure was deferred to the Spring 2020 Consensus Standards Approval Committee (CSAC) due to efforts to reduce burden for committee members who may need to prioritize COVID–19 in their communities.

Regarding the concern that the HWR measure cannot measure individual physicians, the intent of the HWR measure is to measure performance at the clinician group level where the group can assess and improve the performance across their practice. Regarding reliability, the HWR measure was found to have substantial signal to noise reliability, ranging from 0.82 for surgical to 0.92 for neurology specialty cohorts, when clinician groups were measured on at least 200 patients, the minimum threshold for the current ACR measure. While it is true that clinician groups representing different specialties may have different baseline outcome rates because of different patient condition or procedure cohorts, the use of standardized outcome rates for measurement ensures comparability of measure scores across these different cohorts.

After consideration of public comments, we are finalizing our proposal as proposed.

(ii) Incorporating QCDR Measures Into MVPs

In the CY 2020 PFS final rule, we sought comments from stakeholders as to whether QCDR measures should be considered for integration within MVPs. Stakeholders were generally supportive of including QCDR measures within MVPs, but others expressed concern that including QCDR measures within MVPs would require clinicians to use certain third party intermediaries which may cause additional burden for clinicians who may need to change their current reporting method and undertake additional costs associated with reporting through QCDRs. Under the existing MIPS program and as described at § 414.1330(a)(2), for a MIPS payment year, we can use approved QCDR measures as described under § 414.1400 to assess performance in the quality performance category. We continue to believe that the development of QCDR measures by QCDRs is important as it provides measures that are relevant, applicable, and meaningful to clinicians, and addresses gaps that are not addressed by measures available through the MIPS quality measure inventory. In envisioning MVP development for the 2022 performance period and future years, we believe it is important to consider the opportunity to include QCDR measures within MVPs. Prior to consideration of including the QCDR measure within a candidate MVP, QCDR measures must meet all existing criteria under § 414.1400(b)(3) and the criteria described at § 414.1400(b)(3)(v)(C)(*4*) that QCDR measures should be fully tested at the clinician level prior to the QCDR measure being included in an MVP. We referred readers to section IV.A.3.g.(2)(b)(iv) of the CY 2021 PFS proposed rule for additional discussion of this requirement.

Regarding the timeline to which MVPs and QCDR measures may be established, we have identified differences with the timelines that each of these processes follow. As described in the CY 2020 PFS final rule (84 FR 62948), we finalized the definition of an MVP at § 414.1305 to mean a MIPS Value Pathway is a subset of measures and activities established through rulemaking. Furthermore, as described in the CY 2019 PFS final rule (83 FR 59900) and at § 414.1400(b)(1), entities that wish to self-nominate as a QCDR and submit QCDR measures for CMS consideration must do so within the 60-day self-nomination period that begins on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year. QCDR measures are typically reviewed and approved in the preceding months after the close of the self-nomination period. Therefore, we proposed that beginning with the with the 2022 performance period, only QCDR measures that were approved in the previous year may be considered for inclusion within a candidate MVP. Furthermore, we proposed that the QCDR measures included within a candidate MVP must meet the existing criteria that are currently established at § 414.1400(b)(3). In the traditional MIPS program, we stated that entities that meet the QCDR definition can develop QCDR measures to fulfill the quality performance category reporting requirements. We stated that we believe that QCDR measures can continue to fulfill the reporting requirements of the quality performance category within MVPs. Candidate MVPs should be submitted utilizing the process as described in section IV.A.3.a.(2)(a) of the CY 2021 PFS proposed rule. Candidate MVPs that are approved for inclusion in the upcoming performance period must be proposed and finalized through notice-and-comment rulemaking. Candidate MVPs that include QCDR measures will also need to be proposed and finalized through notice-and-comment rulemaking in order to be available for reporting in the upcoming performance period. Therefore, in instances where MVPs are finalized through notice-and-comment rulemaking with QCDR measures, we proposed that those QCDR measures would be eligible for 2-year QCDR measure approval as described at § 414.1400(b)(3)(vi).

In the CY 2018 PFS final rule (82 FR 53813), we finalized that beginning with the 2018 performance period and for future program years, that QCDRs may seek permission from another QCDR to use an existing QCDR measure that is owned by another QCDR.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported inclusion of QCDR measures in MVPs.

Response: We thank the commenters for their support; we believe that expanding the availability of QCDR measures that could be included into MVPs will allow for the development of more innovative and meaningful MVPs that are relevant to specialties and subspecialties.

Comment: One commenter suggested that we consider separating dates for QCDR self-nomination and MVP candidate submission due to the amount of developer financial and administrative resources required.

Response: To clarify, as described in the CY 2019 PFS final rule (83 FR 59898) the QCDR self-nomination starts on July 1st to Sept 1st of the year prior to the performance period. As described in the CY 2021 PFS proposed rule (85 FR 50284), beginning with the 2022 performance period, only QCDR measures that were approved in the previous year may be considered for inclusion in a candidate MVP. As stakeholders develop their MVP candidates, and consider the inclusion of their QCDR measures, only those that were approved for the 2022 performance period could be considered for inclusion. We believe the existing differences in the timeline will help to alleviate some of the administrative resources required for both processes. For example, a QCDR will self-nominate a QCDR measure for the 2022 performance period sometime between July 1, 2021 and September 1, 2021. The 2022 performance period QCDR measure approval decisions will be shared with the QCDRs in late Fall of 2021, with finalization of the QCDR measure specifications by the end of 2021. QCDR measures that are approved

for the 2022 performance period, and have been fully tested, may be considered for inclusion in MVPs for the 2023 performance period through the rulemaking process that will occur throughout CY 2022. MVPs that include QCDR measures, which are finalized through the CY 2023 PFS final rule, will be tracked to, and those QCDR measures will be given multi-year approval, so that the QCDR will not have to self-nominate that measure during self-nomination for the 2024 performance period.

Comment: A few commenters supported approval of Qualified Clinical Data Registry (QCDR) measures for 2 years or longer to promote burden reduction and continuity. One commenter supported maintaining MVP QCDR measure approval for 2 years unless the measure steward agrees with a change in approval status. The commenter voiced support for removing a measure if it reflects an outdated clinical deadline or if the QCDR that nominated the measure is no longer in good standing but does not support CMS removing a measure before its second year for it being topped out or duplicative of a more robust measure.

Response: We thank the commenters for their support, but note that a change in a QCDR measure's approval status will be left at the discretion of CMS, and as long as the QCDR measure continues to meet the criteria described at § 414.1400(b)(3)(vi). We disagree that QCDR measures that are identified as topped out or duplicative of a more robust measure should not be removed as it is contradictory to the Meaningful Measure Framework. Measures that are topped out provide limited to no value to quality improvement, and duplicative measures serve no purpose in quality measurement.

Comment: A few commenters did not support our proposal to require QCDR measures be approved for use in MIPS for a year prior to being included in an MVP voicing a concern that this will delay use of meaningful QCDRs measures in MVPs. Another commenter suggested that instead of the proposed 1-year period prior to measure inclusion in MVPs, that QCDR measures be tested entirely before inclusion in an MVP.

Response: We disagree and believe that in order for a QCDR measure to be considered a QCDR measure, it must be approved as such through the Self-Nomination process prior to being proposed through notice and comment rulemaking as a part of an MVP. Measures that do not undergo this process are not considered QCDR measures until they are formally approved as such. Furthermore, to provide clarity, we proposed in the CY 2021 PFS proposed rule (85 FR 50284) that any QCDR measure that is being considered for inclusion in an MVP, must be fully tested before it can be included, as we want to ensure that the measures included in MVPs are a reliable subset of the MIPS measure inventory.

Comment: One commenter suggested, as a way to shorten the timeline, that we consider allowing stakeholders to submit MVPs that include QCDR measures that are simultaneously undergoing approval with final inclusion in an MVP pending their meeting full testing and reliability requirements and receiving final approval.

Response: We disagree, as the differences in the timelines between QCDR measure approvals through the Self-Nomination process and the timeline for notice and comment rulemaking differ, and would not allow for sufficient time to review the results to determine whether a QCDR measure is reliable, feasible, and valid enough for inclusion in an MVP. We are concerned with the unintended consequences of simultaneously including QCDR measures within MVPs before they are approved. If the QCDR measure is not approved through self-nomination, we would not be able to finalize the inclusion of the QCDR measure within the MVP. Time will be needed to determine the implications of the QCDR measure not being finalized in the MVP, and whether there are sufficient number of measures available in the MVP in the event that the QCDR measure cannot be included. Since MVPs will allow for the creation of focused subsets of measures and activities on a given clinical topic, thereby focusing the choices available to clinicians, we believe that all measures included in MVPs should have to meet and pass full measure testing criteria inclusive of reliability, validity, and feasibility. QCDR measures that pass measure testing are considered to be more reliable, we are concerned that incomplete testing will have downstream impacts to clinicians who may not be able to successfully report on measures, or that it may result in skewed results that may impact payment adjustments. Therefore, it would be appropriate to wait until the QCDR measure is officially approved through the self-nomination process before it is considered and finalized for inclusion in an MVP through notice and comment rulemaking.

Comment: One commenter suggested that we use the 2020 performance year QCDR measure approval standards for MVP QCDR measures, and stated that data for reliability and performance rates are often more robust after the QCDR measure has been available for MIPS reporting for at least 1 year.

Response: We disagree. The 2020 performance period QCDR measure approval standards do not currently include QCDR measure testing requirements. Our preference is to include QCDR measures in MVPs only after they have been fully tested and are comparable in standard to the measures within the MIPS quality measure inventory that have undergone vigorous testing.

Comment: One commenter requested further clarification related to how QCDR measures will be selected for MVPs to ensure measures are most relevant, applicable and meaningful to clinicians. The commenter requested that CMS clarify the impact to an MVP if CMS revokes the QCDR measure's second year of approval. The commenter voiced concerns related to the lack of incentives for clinicians to use new QCDR measures that require significant financial and administrative resources to develop and requested support for inclusion of these new QCDR measures.

Response: QCDR measures can be included in MVPs at the discretion of the stakeholder developing the MVP candidate. We refer readers to our previously established policies in the CY 2018 PFS final rule (82 FR 53813), where we finalized that beginning with the 2018 performance period and for future program years, that QCDRs may seek permission from another QCDR to use an existing QCDR measure that is owned by another QCDR. If a QCDR measure approval is revoked for an upcoming performance period, the QCDR measure will be simultaneously proposed for removal from the MVP. As a part of the MVP maintenance process, there may be consideration of including another measure in the QCDR measure's place. To clarify, new QCDR measures can be considered for inclusion in an MVP so long as the measure has met all requirements.

Comment: One commenter voiced concerns regarding burden associated with completing the third party intermediary self-nomination application prior to publication of the QPP final rule and then selecting which MVPs to support after publication of the final rule. To address this concern, the commenter suggested a 1-year delay between selecting the MVPs that QCDRs and qualified registries can support and beginning the reporting for an MVP, and separating the dates for completion of the QCDR self-nomination and the MVP self-nomination.

Response: We disagree that there would be additional burden associated with the process of having approved QCDRs and qualified registries indicate whether they are supporting any of the finalized MVPs once the final rule is published. We believe a 1-year delay would be a disadvantage, because it delays the timing in which a third party intermediary can support an MVP. The timing of when QCDRs would approve their qualified postings typically aligns with the timing of the posting of the final rule; therefore, QCDRs would be able to select the MVPs they wish to support for the upcoming performance period based on the final rule publication, and have those MVPs included in their qualified posting before it is published by January 1st of the performance period.

After consideration of the public comments, we are finalizing our proposals as proposed.

(c) Reporting of MVPs Through Third Party Intermediaries

Through the MIPS program, QCDRs, qualified registries, and Health IT vendors support the reporting of the Quality, Promoting Interoperability, and Improvement Activity performance categories, as proposed and codified at § 414.1400(a)(2). We believe that third party intermediaries who support the aforementioned performance categories are able to support MVPs, since they will be comprised of measures and activities from these performance categories, as well as cost measures that are calculated by CMS (thereby requiring no additional effort by third party intermediaries). We believe allowing third party intermediaries to support MVPs will offer eligible clinicians and groups additional methods to report an MVP. We refer readers to section IV.A.3.g. of this final rule for additional discussion of the proposals.

Since QCDR and qualified registry applicants would be submitting their self-nomination application prior to the publication of the final rule, we will work to establish a process to allow QCDRs and qualified registries to identify and select which MVPs they can support following the publication of the final rule. We sought comments on the proposal.

The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed that third party intermediaries should be allowed to support MVP reporting.

Response: We thank the commenters for their support, and agree that third party intermediaries should be allowed to support the reporting of MVPs. Clinicians and groups may find it beneficial to utilize a third party intermediary to report an MVP for the additional support they may provide.

Comment: One commenter cautioned that the use of third party intermediaries for MVPs could result in financial burden for practices required to purchase additional measure submission services.

Response: We understand that there may be some financial burden associated with utilizing a third party intermediary to report MVPs; however, we note that clinicians and groups are not required to utilize a third party intermediary to report an MVP. Clinicians and groups may use existing reporting options to report on the measures and activities within an MVP without utilizing a third party intermediary.

After consideration of the public comments, we are finalizing our proposals as proposed.

(3) Transition to MVPs

(a) Timeline for MVP implementation

In response to the RFI in the CY 2020 PFS final rule, we have received comments from stakeholders that indicated a gradual implementation of MVPs. Through the MVP development process, we seek to collaborate with stakeholders in the development of MVPs that are meaningful and applicable to clinicians and groups. Therefore, we understand the need for an incremental approach as we transition eligible clinicians and groups to MVP reporting as they are implemented. In light of the PHE of COVID–19, we have decided to delay the implementation of MVPs, and revisit potential MVP implementation through future rulemaking, possibly beginning with the 2022 performance period. Although we believe in the importance of transforming the MIPS program to create greater meaning for clinicians, we understand that there are clinicians who are on the frontlines taking care of COVID–19 patients that should not be burdened with having to learn a new method of reporting for the MIPS program at this time. Overall, our goal is to gradually implement MVPs for all MIPS eligible clinicians and groups overtime, to ensure that MVPs are designed and available in a manner relevant to clinicians. We stated that we intend to continue to work closely with stakeholders to develop MVPs that are relevant to various specialties, and understand that a level of flexibility is needed to allow for meaningful reporting.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to delay MVP Implementation as a result of the PHE for COVID–19, and recommended that CMS introduce MVPs gradually.

Response: We thank commenters for their support, as described in the CY 2021 PFS proposed rule (85 FR 50279), we have delayed our timeline for MVP implementation in light of the PHE for COVID–19. We want to move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the COVID–19 pandemic. Furthermore, as described in the CY 2021 PFS proposed rule (85 FR 50284 through 50285), we understand the need for an incremental approach as we transition clinicians and groups to MVP reporting as they are implemented.

Comment: A few commenters recommended that MVPs be delayed beyond 2022 as well, yet did not cite specific reasons why.

Response: While we appreciate the commenters concerns, we believe that further delay is not needed as we have emphasized the need for an incremental approach to transition clinicians and groups to MVP reporting.

After consideration of public comments, we are finalizing our proposals as proposed.

b. APM Performance Pathway

(1) Overview

In the CY 2020 PFS final rule (84 FR 62568), we finalized the MIPS Value Pathway framework as a means of reducing reporting burden, increasing meaningful measurement, and continuing to encourage movement through MIPS away from fee-for-service (FFS) payments and towards APMs. Burden reduction and meaningful measurement are important goals in relation to all eligible clinicians, and we recognize that the best means for achieving these goals may be different for MIPS eligible clinicians that have not yet joined an APM than for those MIPS eligible clinicians who already are participating in APMs, and therefore, have different reporting obligations. This is particularly true for eligible clinicians in Advanced APMs who are subject to MIPS either because they are Partial QPs for a year and elect to participate in MIPS or because they fall below the applicable Partial QP threshold for a performance year.

We proposed at § 414.1367 to establish an APM Performance Pathway (APP) under MIPS beginning in the

2021 MIPS performance year, designed to provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation (85 FR 50285).

(2) Applicability

We proposed that the APP will be in effect beginning January 1, 2021, and would be an optional MIPS reporting and scoring pathway for MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the four snapshot dates (March 31, June 30, August 31, and December 31) during a performance period, beginning in the 2021 MIPS performance period.

(a) Reporting Through the APM Performance Pathway

We proposed that individual MIPS eligible clinicians who are participants in MIPS APMs may report through the APP at the individual level. Groups and APM Entities may report through the APP on behalf of their constituent MIPS eligible clinicians; however, the final score earned by the group through the APP would be applied only to those MIPS eligible clinicians who appear on a MIPS APM's Participation List or Affiliated Practitioner List on one or more snapshot dates. The final score applied to each individual MIPS eligible clinician would be the highest available final score for that clinician (TIN/NPI), or a Virtual Group score, if applicable, as discussed in the CY 2021 PFS proposed rule (85 FR 50315).

As described further in the CY 2021 PFS proposed rule (85 FR 50231), ACOs participating in the Medicare Shared Savings Program would be required to report through the APP for purposes of assessing their quality performance for that program, but MIPS eligible clinicians participating in these ACOs also would have the option of reporting outside the APP, or within it at an individual or group level, for purposes of being scored under MIPS, like all other MIPS APM participants. As the APP would be optional for purposes of MIPS scoring, under the proposal MIPS APM participants would be able to report through the APP or through any other available MIPS reporting mechanism they chose.

We refer readers to the CY 2021 PFS proposed rule (85 FR 50315) for information concerning our proposed changes to the hierarchy that will apply when more than one final score is associated with a TIN/NPI.

We received the following comments on these proposals.

Comment: A few commenters supported the opportunity for individual MIPS eligible clinicians and groups that participate in MIPS APMs to report through the APP or through any other available MIPS reporting mechanism they choose. They believe this approach would enable them to earn a higher score where they perform above the APM Entity average.

Response: We thank commenters for their support of this proposal. We agree that this approach should enable MIPS eligible clinicians and groups that strive to improve their performance to be rewarded with the MIPS score that reflects those efforts. We also believe that this policy approach will create more flexibility for multispecialty practices to report on measures that are the most meaningful to their clinicians.

After considering public comment, we are finalizing this policy as proposed.

(b) MIPS APMs

In the CY 2021 PFS proposed rule (85 FR 50285), we proposed to amend our definition of MIPS APM at § 414.1305 as an APM that meets the criteria in § 414.1367(b). We also proposed to codify the following MIPS APM criteria at the new § 414.1367(b). We proposed to maintain two criteria for MIPS APMs that currently are included at § 414.1370(b)(1) and (3) respectively, namely that: (1) An APM Entity participates in the APM under an agreement with CMS or through a law or regulation; and (2) the APM bases payment on quality measures and cost/utilization. However, under the proposed policy, for purposes of the MIPS performance period we would not depend on the availability of quality measure data reported directly to the APM, and we did not propose to continue requiring that MIPS APMs be in operation, and therefore, collecting quality data for the entirety of the performance period. We also noted that currently, to be a MIPS APM, § 414.1370(b)(2) requires that an APM must be designed such that its APM Entities include at least one MIPS eligible clinician on a Participation List, and does not include APMs that use only Affiliated Practitioner Lists. However, we believe that because we did not propose to require reporting through the APP be done exclusively at the APM Entity level, it is not necessary to limit use of the APP to APM Entities alone. Therefore, we proposed to expand the definition of MIPS APM to include those APMs in which there is only an Affiliated Practitioner List and that otherwise meet the proposed MIPS APM criteria.

We did not receive any comments on these proposals and are finalizing as proposed.

(3) MIPS Performance Category Scoring in the APM Performance Pathway

In general, MIPS reporting and scoring requirements are applicable to all MIPS eligible clinicians, including those reporting through the proposed APP. However, the following reporting and scoring rules would apply only to those MIPS eligible clinicians, groups, or APM entities reporting through the APP.

(a) Quality Performance Category

We proposed that, beginning in the 2021 performance period, MIPS eligible clinicians scored under the APP would be scored on the quality measure set finalized for such MIPS performance period (85 FR 50285 through 50286).

For PY 2021, we proposed to use the measures listed in Table 46 for purposes of quality performance category scoring for the APP.

TABLE 46: APM Performance Pathway Quality Measure Set

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Quality ID:001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID: 236	Controlling High Blood Pressure	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions

For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we proposed to remove such measure from the quality performance category score for such MIPS eligible clinician, group, or APM Entity.

For MIPS eligible clinicians, groups, or APM Entities reporting through the APP, we proposed not to apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP measure set is determined to be topped out. Because the measure set is fixed, we noted that we do not believe it is appropriate to limit the maximum quality performance category score available to them. Should an APP measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

In the CY 2020 PFS proposed rule, we sought comment on aligning the Shared Savings Program version of the Multiple Chronic Conditions (MCC) measure (that is, the ACO MCC) with the MIPS version of the MCC measure (see 84 FR 40711 and 40712). We noted that the MIPS MCC claims-based measure is similar to the ACO MCC currently used to assess ACO quality under the Shared Savings Program. The MIPS MCC and ACO MCC measures are similar because they both target patients with multiple chronic conditions, but the cohort, outcome, and risk model for the MIPS MCC measure varies from the ACO MCC measure. The cohort for the ACO MCC measure includes eight conditions whereas the MIPS MCC measure includes nine conditions, with the additional condition being diabetes. The ACO MCC measure does not adjust for social risk factors whereas the MIPS MCC measure adjusts for two area-level social risk factors: (1) AHRQ socioeconomic status (SES) index; and (2) specialist density. In 2019, we added a revised ACO MCC measure to the 2019 Measure under Consideration list for the Shared Savings Program for consideration by the Measure Applications Partnership (MAP) Clinician Workgroup. The revised MCC measure specifications aligned with the MIPS MCC measure by: (1) Adding a diabetes cohort; (2) excluding any admissions within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility; and (3) adjusting for the AHRQ SES index and specialist density social risk factors. The only remaining difference between the MIPS and Shared Savings Program versions of the measure would be attribution, which is program-specific. Attribution for Shared Savings Program ACOs uses the Shared Savings Program beneficiary assignment methodology, which emphasizes primary care. During the MAP discussion, it was noted that the original ACO MCC measure has been in use in the Shared Savings Program since 2015, and the MAP expressed no concerns with respect to feasibility and implementation of the revised MCC measure. A measure has high reliability if it produces consistent results from multiple measurements, in other words, it reflects a signal, rather than random error associated with measurement. Reliability values range between zero (all error, little signal) to 1.0 (no error, all signal).[121] The median signal-to-noise reliability for all Shared Savings Program ACOs in 2018 was 0.96 ranging from 0.12 to 1.00 (IQR: 0.94–0.98), indicating an overall excellent reliability of the measure.[122]

The MAP final recommendation for this measure was ''conditional support for rulemaking.'' [123] We intended to take the revised measure through the National Quality Forum (NQF) endorsement process in 2020, but as a result of delays caused by the PHE for COVID–19, we will defer seeking NQF endorsement until 2021. Because the revisions would make the ACO MCC measure more aligned with the MIPS version and given the support received from the MAP, we proposed to include the revised All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure in the APP measure set to be reported on by any Medicare ACO.

We received the following comments on the proposal.

Comment: Some commenters requested clarification as to what would

[121] Adams, John L., Ateev Mehrotra, and Elizabeth A. McGlynn, Estimating Reliability and Misclassification in Physician Profiling. Santa Monica, CA: RAND Corporation, 2010. *https://www.rand.org/pubs/technical_reports/TR863.html.*

[122] CMS used the 2018 Shared Savings Program ACO beneficiary assignment data to test the revised MCC measure. Here, reliability refers to measure score reliability of the revised MCC measure.

[123] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

happen if they were unable to report on one or more measures due to submitter type or case size limitations.

Response: Individual MIPS eligible clinicians, groups, and APM Entities reporting through the APP will be scored only on those quality measures on which they are able to report. For example, an APM Entity that is not an ACO will not be scored on the ACO MCC measure; similarly a group that did not meet the minimum beneficiary sample size for the CAHPS for MIPS survey would not be required to report on this measure. In these cases that measure would be removed from the quality performance category score calculation entirely.

Comment: Some commenters expressed concern that the proposed measures do not adequately reflect the scope of practice of all clinicians, particularly specialists, and suggested that we consider expanding the quality measure set to include specialty-specific quality measures, or retaining the use of the quality measures from their APMs, as was done under the APM scoring standard.

Response: We recognize that there are limitations in the ability of the proposed APP quality measure set to fully represent the scope of practice of all specialties and clinicians. However, the goal of the APP quality measure set is not necessarily to reflect the specific quality measure work being done by these clinicians within their respective APMs, but rather to reduce the burden of reporting on quality measures twice: once to MIPS and once to their APMs. We believe by using this broadly applicable population health based measure set, we will enable MIPS APM participants to focus more of their energy and attention on the quality measures being reported through their APMs, while relying on a consistent measure set within the APP from one year to the next. We further refer readers to CY 2020 PFS final rule (84 FR 63007) for a discussion around the operational infeasibility of continuing to use quality measure data reported directly to APMs.

Comment: Some commenters noted confusion about which submission types would be permitted under the APP.

Response: As defined at § 414.1305, submission type refers to the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. In Table 41 of the CY 2021 PFS proposed rule (85 FR 50286) we proposed a list of quality measures that would be included in the APP. For those measures in this list that are already included in the MIPS quality measure inventory (Quality IDs 001, 134, and 236) the previously established submission types for each measure would continue to be accepted, including by the APM Entity, as applicable, which we proposed to add as a submitter type. We note that the CAHPS for MIPS survey may only be reported by a Third Party Intermediary. For those measures that are not already included in the MIPS quality measure inventory (Quality IDs TBD), the proposed measures are administrative claims-based and do not require data submission

Comment: A few comments supported the proposed APP quality measure set for reducing burden on MIPS eligible clinicians who are also participating in MIPS APMs. Commenters noted that the measures selected represent a broad sampling of practice areas, and should be applicable to nearly any practice group.

Response: We thank the commenters for their support.

Comment: A few commenters objected to the use of two administrative claims measures, relative to the number of non-claims measures. These commenter noted a preference for more performance-based measurement that would be reported by the MIPS eligible clinician, group, or APM Entity.

Response: We understand the concern about the use of more administrative claims measures in the APP quality set, in light of the fact that, historically, these measures produce somewhat lower scores than measures such as those in the CMS Web Interface which are largely topped-out. It is our intent to balance the goals of reducing reporting burden while incentivizing increased quality performance by including in the APP measure set measures that will represent quality performance without creating additional reporting burden. We believe the proposed measure set, and the relative weight of the different submission types, helps to strike that balance.

Comment: Some commenters expressed support for the move to all-payer data for scoring MIPS quality measures for ACOs. These commenters believe that the all-payer data will more accurately reflect the efforts they have made to improve quality performance across their practice.

Response: We agree that by incorporating all-payer data into both the numerator and the denominator, we will be getting a better picture of each MIPS eligible clinician's quality performance across care settings, and incentivizing quality improvement for all patients.

Comment: Commenters recommended that CMS seek NQF and MAP endorsement of any measure to be included in the APP before the measure is included in the APP. Additionally, commenters suggested that CMS seek additional stakeholder input and were concerned that the Measure Applications Partnership did not review these proposed changes.

Response: With regard to the commenters' recommendations that we use measures that are NQF endorsed and have been reviewed by the AMP, we note that where possible CMS uses measures that have been NQF endorsed. In the APP measure set, the three eCQM/CQM measures are NQF endorsed and we plan to take the revised MCC measure that was reviewed by the MAP in December 2019 through the NQF endorsement process in 2021.

Comment: Several commenters have concerns with the Screening for Depression and Follow-up plan measure and recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. One commenter did not support the measure because it was not an outcome measure, and shared concerns that it had previous measurement challenges. Additionally, one commenter noted that depression screening can be difficult to achieve with the limited access that the PHE for COVID–19 has created and suggested that measures be viewed through the lens of the current environment.

Several commenters expressed concerns that this measure determines performance based on a single reading and that there are limitations in accepting patient reported home readings. The commenters also recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. Another commenter recommended that CMS consider including home visits in its measure sets. One commenter supported the Controlling High Blood Pressure measure, noting that successfully treating high blood pressure can save lives.

One commenter was concerned that the Diabetes: Hemoglobin A1c (CbA1c) Poor Control measure is not appropriate for frail, seriously ill, or home limited patient populations. Another commenter supported this measure, citing the fact that uncontrolled diabetes leads to comorbidities.

Response: We appreciate the commenters' feedback on these eCQM/CQM MIPS measures. This measure set was developed using stakeholder

feedback and in conjunction with CMS leadership to help achieve the goals of the APP. Each of the eCQM/CQM quality measures in the APP measure set is MIPS quality measures that has been in use for several MIPS performance years and have a track record of reliability that was taken into consideration when choosing the APP measure set. We believe that this particular set of measures best achieves our goal of reducing reporting burden while providing a quality measure set with measures that are meaningful and widely applicable to various provider types. As with all MIPS quality measures, we encourage continued stakeholder engagement in developing and improving upon measure use and specifications.

Comment: One commenter provided general support for the concept of measuring outcomes for patients with multiple chronic conditions at the group practice level or higher and provided support for the specific methodological changes proposed, including incorporating additional risk factors related to socioeconomic status and social risk factors. Several commenters expressed concerns related to the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs measure. One commenter did not support using this measure to assess the quality performance of ACOs because they noted the Core Quality Measures Collaborative (CQMC) ACO/Patient-Centered Medical Home (PCMH) core measure set would be less burdensome and would align the measures across public and private payers, making it a better measure set for ACOs. Some commenters stated that this measure does not meet the −.8 reliability threshold because the measure score reliability ranged from 0.12 to 1.00 using data from the 2018 performance year. Therefore, this commenter recommended that CMS increase testing for risk adjustment, increase case minimums, and demonstrate face validity (whether these measures appear to measure what they claim to measure) and that the results are valid when attributed to an ACO. The commenter also recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. Another commenter opposed inclusion of this measure in the quality measure set under the APP due to limited information on how the measure performs and because it has not been endorsed by the NQF. The same commenter recommended that CMS increase the minimum sample size to produce a minimum reliability threshold of sufficient magnitude and encouraged CMS to validate the measure through additional testing, such as predictive and construct validity, to ensure that application of the measure to assess the quality performance of ACOs is appropriate and yields scores that are valid and useful.

Another commenter was encouraged to see that the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) index and density of physician specialists were included in the risk adjustment for the measure in the 2018–2019 Measures Application Partnership (MAP) review. This commenter emphasized that CMS should ensure that social risk factors are tested and included in the risk adjustment for the measure and that CMS should also consider including additional variables, such as dual eligibility, frailty, and age, prior to implementing the measure in the APP.

Response: The All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions for ACOs)—the ''ACO MCC'' measure is currently being used to assess ACOs' quality performance under the Shared Savings Program. The proposed MCC measure was created by aligning the current ACO MCC measure with the current MIPS MCC measure by (1) adding a diabetes cohort; (2) excluding any admissions within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility; and (3) adjusting for the AHRQ SES index and specialist density social risk factors. The MAP expressed no concerns with respect to implementing this measure and, as discussed in the CY 2021 PFS proposed rule (85 FR 50286), the median signal-to-noise reliability for all ACOs scored on this measure in 2018 was 0.96 ranging from 0.12 to 1.0 (IQR: 0.94–0.98), indicating an overall excellent reliability of the measure. This measure is currently under NQF review.

We believe that this measure will provide a meaningful assessment of ACO quality performance with limited additional reporting burden.

Comment: Many commenters were opposed to sun-setting the CMS Web Interface and its use under the APM scoring standard. Several commenters expressed concern about the timeline for preparing to report APM Entity level data for the 3 eCQM/MIPS CQMs in time for the 2021 performance year. Specifically, ACOs may face difficulty in aggregating the data needed for reporting, particularly in light of the PHE for COVID–19.

Response: We understand that implementing a new reporting system will require administrative time and coordination in order to be prepared not only for reporting APM Entity level data, but for collecting these data as early as January 1, 2021. Particularly in light of the circumstances surrounding the PHE for COVID–19, we believe that it is in the public interest to finalize our proposed quality measure set with a few modifications to include the CMS Web Interface for one year.

After considering public comment, we are finalizing each of the quality measures included in the quality measure set listed in Table 41 of the CY 2021 PFS proposed rule (85 FR 50286).

In addition, we refer readers to section IV.A.3.c.(1)(c) of this final rule, where we are finalizing our proposal to remove the CMS Web Interface with a 1 year delay. As a result, the CMS Web Interface measure set will not be removed until the CY 2022 MIPS performance period. In response to public comments, we are finalizing the addition of the CMS Web Interface measure set to the proposed APP quality measure set for the CY 2021 MIPS performance period for ACOs only. We are limiting the extension of the CMS/Web Interface to those Entity types which, in the past, have used the CMS Web Interface for purposes of MIPS reporting, and may therefore benefit from a transitional year before reporting via a new submission type. Groups and other APM Entity types that have in the past been scored using different submission types do not face the same obstacles, and therefore do not require a transition year.

Each individual MIPS eligible clinician, group, and APM Entity reporting through the APP will be scored on the ACO MCC measure, Hospital-wide Readmission measure, and CAHPS for MIPS survey, as applicable. In addition, individual MIPS eligible clinicians and groups reporting through the APP will be required to report on the three eCQMs/MIPS CQMs included in the APP quality measure set. APM Entities reporting through the APP will be required to report on either the three eCQMs/MIPS CQMs included in the APP quality measure set or on the CMS Web Interface measure set. We refer readers to Appendix 1 for additional measure specification information.

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TABLE 47: Measures included in the Final APM Performance Pathway Measure Set+

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

+ We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) do not have benchmarks and are therefore not scored; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2021 MIPS Performance year only.

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We are finalizing at § 414.1367(c)(1) the quality measure set for the APP, and are adding the option for ACOs to report on the CMS Web Interface for the 2021 performance year only.

(b) Cost

In the CY 2017 Quality Payment Program final rule (81 FR 77256, 77265), we finalized at § 414.1370(g)(2) to waive the cost performance category under waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs, and at section 1899(f) of the Act for the Medicare Shared Savings Program. We proposed to continue to waive the cost performance category under the same authorities for three reasons. First APM entities in MIPS APMs already are subject to cost performance assessment under their APMs, as the MIPS APM criteria would continue to include the assessment of participants based on cost. Second, MIPS APMs may measure cost performance in different ways than MIPS, for example, by basing cost on total cost of care, which measures a broader scope of cost or resource use than would necessarily be reflected in the narrower claims-based accountability standard under MIPS. Finally, MIPS APMs may attribute beneficiaries differently from MIPS for purposes of measuring cost, leading to an unpredictable degree of overlap between the sets of beneficiaries for whom the MIPS eligible clinicians

would be responsible under their APM and under MIPS. We noted that we believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population under the APM, it is necessary to give the APM Entity the ability to identify a single beneficiary population to prioritize in its cost-saving efforts. This is necessary so that the goals and evaluation associated with the APM are as clear and free of confounding factors as possible. With this flexibility, we noted that MIPS eligible clinicians who are attempting to strategically transform their respective practices would not jeopardize their ability to succeed in either MIPS or under the terms of their APM. Therefore, by participating through the APP, the APM participant may indicate their intent to focus their resources on the beneficiary population and services identified by the terms of the APM rather than the population and services they would have been responsible for under the MIPS cost performance category.

We received the following comments on this proposals.

Comment: Commenters supported the proposal, noting that as APM participants they are already being assessed on cost performance under the terms of participation in their APM.

Response: We thank commenters for their support. We refer readers to section IV.A.3.e. of this final rule, for additional discussion around the reweighting of the cost performance category for APM Entities that choose to report to MIPS outside of the APP.

After considering public comments, we are finalizing this policy as proposed.

(c) Improvement Activities

We proposed to assign a score for the Improvement Activities performance category for each MIPS APM, and that score will be applied to participant MIPS eligible clinicians reporting through the APP. In an effort to further reduce reporting burden for MIPS eligible clinicians in MIPS APMs and to better recognize improvement activities work performed through participation in MIPS APMs, we proposed to assign a baseline score for each MIPS APM based on the improvement activity requirements of the particular MIPS APM. CMS would review the MIPS APM's requirements in relationship to activities specified under the generally applicable MIPS improvement activities performance category and assign for each MIPS APM an improvement activities performance category score that is applicable to all MIPS eligible clinicians reporting through the APP who are participants in the MIPS APM. To develop the improvement activities score for MIPS APMs, we would compare requirements of the APM with the list of Improvement Activities, described in § 414.1355(a), for the applicable year, and score those improvement activities as they would otherwise be scored according to § 414.1380(b)(3). Thus, as proposed, points assigned to an APM participant MIPS eligible clinician participating in MIPS through the APP would be based, at least in part, on the documented terms and requirements of participation in the MIPS APM, such as under a participation agreement or regulation. In the event a MIPS APM participant does not actually perform an activity for which Improvement Activities credit would otherwise be assigned under the proposal, the MIPS APM participant would not receive credit for the associated Improvement Activity.

We noted that we would publish the assigned improvement activities scores for each MIPS APM on the CMS website prior to the beginning of the MIPS performance period. In the event that the assigned score for a MIPS APM does not represent the maximum improvement activities score, we proposed that MIPS eligible clinicians reporting through the APP would have the opportunity to report additional improvement activities that then would be applied towards their scores.

We noted that under section 1848(q)(5)(c)(ii) of the Act, a MIPS eligible clinician in an APM for a performance period automatically earns a minimum score of one half of the highest potential score for the improvement activities category for their participation in an APM for the performance period. Additionally, under section 1848(q)(5)(c)(i) of the Act, MIPS eligible clinicians participating in a patient-centered medical home model or comparable specialty practice, as determined by the Secretary for a performance period, automatically earn the highest potential score for the improvement activities category. These baseline scores would be automatically applied for all MIPS eligible clinicians who participate in an APM in accordance with § 414.1380(b)(3)(i) and (ii), respectively.

We sought comment on the proposal.

Comment: One commenter expressed confusion about the improvement activities reporting requirements for MIPS eligible clinicians reporting through the APP. Specifically, how participants of a MIPS APM would know when they are required to report additional improvement activities for MIPS scoring.

Response: In past years, and in the 2021 performance year, we have identified all MIPS APMs as having met the improvement activity threshold score requirement to receive a score of 100 percent for that performance category. In the event that in the future an APM does not meet this threshold, we would allow participants in that APM to report additional quality measures in order to earn a score of up to 100 percent for that performance category.

Similarly, should we learn that a MIPS eligible clinician or group has reported through the APP, but we discovered that their APM Entity has failed to complete the required improvement activities and any CAP developed as a result of this discovery, participants in that APM Entity may be subject to an audit wherein they would have the opportunity to produce evidence that they have completed sufficient improvement activities to maintain their performance category score of up to 100 percent. If it is determined that participants in such APM Entity did not complete enough improvement activities to earn a score of 100 percent, their performance category score will be recalculated. We note that the statute assigns a minimum improvement activities performance category score of 50 percent to all APM participants.

After considering public comments, we are finalizing the policy as proposed.

(d) Promoting Interoperability

We proposed that the Promoting Interoperability performance category score would be reported and calculated in the same manner described at § 414.1375. We sought comment on the proposal.

Comment: One commenter suggested that we enable ACOs to report the PI performance category.

Response: As in past years, it is not currently operationally feasible for CMS to accept PI performance category reporting at the APM Entity level in cases where an APM Entity is comprised of more than one TIN. However, we continue to reassess this issue annually, and we welcome stakeholder input on how we might implement changes of this sort in future program years.

After considering public comment, we are finalizing the policy as proposed.

(4) APP Performance Category Weights

We proposed to continue to waive the requirement to weight each MIPS performance category as described in

section 1848(q)(5)(E) of the Act using the waiver authority in sections 1115A(d)(1) and 1899(f) of the Act for CMS Innovation Center APMs and the Medicare Shared Savings Program, respectively. For reasons described in the CY 2021 PFS proposed rule (85 FR 50287), we stated that we believe it is necessary to waive the cost performance category for MIPS eligible clinicians reporting to MIPS through the APP. As a result, we stated that it also would be necessary to waive the requirement to weight each MIPS performance category as described in section 1848(q)(5)(E) of the Act and to redistribute the cost performance category weight to the remaining performance categories to be scored for APM participants reporting through the APP.

We proposed to reweight the performance categories for APM participants reporting through the APP to:

- *Quality:* 50 percent
- *Cost:* 0 percent
- *Promoting Interoperability:* 30 percent
- *Improvement Activities:* 20 percent

We noted that we believe these weights are appropriate as they generally align with the relative performance category weights under MIPS and MVPs in circumstances where the cost performance category has been reweighted to zero percent of the final score, and the cost performance category weight has been distributed proportionately among the remaining performance categories.

We proposed to codify these proposals at § 414.1367(d)(1). We did not receive any comments on these proposals, and we are finalizing them as proposed.

(a) Reweighting a Performance Category

We recognize that there are certain circumstances when a MIPS eligible clinician, group, or APM Entity may be unable to complete reporting to MIPS due to, for example, extreme and uncontrollable circumstances, hardship, or the unavailability or inapplicability of measures due to practice size or other data limitations. Therefore, under the authority provided in section 1848(q)(5)(F) of the Act, it may become necessary to reweight one or more performance categories.

In a case where the Promoting Interoperability performance category is reweighted to zero percent, we proposed to reweight the quality performance category to 75 percent and the Improvement Activities performance category to 25 percent.

In a situation where the quality performance category is reweighted to zero percent, we proposed to reweight the Promoting interoperability performance category to 75 percent and the improvement activities performance category to 25 percent.

We noted that we believe that the distributions appropriately value performance categories that require reporting on measures and measuring improvement, without disproportionately emphasizing one performance category over another. Furthermore, the performance category weights will contribute to a unified performance category reweighting policy throughout MIPS in the event of an Extreme and uncontrollable circumstance that requires the reweighting of cost and any other MIPS performance category.

We proposed to codify this policy at § 414.1367(d)(2). We did not receive any comments on this proposal, and therefore, we are finalizing as proposed.

(5) Scoring for APM Participants Reporting Through the APP

We proposed that final scoring for APM participants reporting to MIPS through the APP would follow the same methodology as established for MIPS generally at § 414.1380. Specifically, we noted that we would continue to score each performance category and multiply each performance category score by the applicable performance category weight, and then calculate the sum of each weighted performance category score and apply any applicable adjustments.

We proposed to codify this policy at § 414.1367(e). We did not receive any comments on this proposal, and therefore, we are finalizing as proposed.

(6) Performance Feedback for APM Participants Reporting Through the APP

We proposed to make performance feedback available to MIPS eligible clinicians reporting through the APP according to the methods applicable to all MIPS eligible clinicians, as described in the 2017 QPP final rule (81 FR 77347). We did not receive any comments on this proposal, and therefore, we are finalizing as proposed.

c. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

We refer readers to §§ 414.1330 through 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

In the CY 2021 PFS proposed rule (85 FR 50288), we proposed to:

- Weight the quality performance category at 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year, at § 414.1330(b)(4) and (5), respectively.
- Sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period.
- Make changes to the MIPS quality measure set as described in Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50413 through 50665), including addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.
- Establish separate performance periods specific to administrative claims measures at § 414.1320(d)(1).
- Make changes to the CAHPS for MIPS Survey to address the increased use of telehealth care.
- Expand telehealth codes used in beneficiary assignment for the CAHPS for MIPS Survey beginning with the performance year 2021 survey.

(b) Weight in the Final Score

Section 1848(q)(5)(E)(i)(I) of the Act, provides that 30 percent of the final score shall be based on performance for the quality performance category, in which the percentage points attributed to the final score for the quality and cost performance categories will both be equivalent at 30 percent, totaling 60 percent of the final score. The percentage points attributed to both the quality and cost performance categories are in tandem. For each year within the first 5 years of the MIPS program, the quality performance category performance percentage can be increased to more than 30 percent of the final score. The percentage increase of the quality performance category is equivalent to the decrease of the cost performance category.

As discussed in the CY 2021 PFS proposed rule (85 FR 50293 through 50294), we proposed to weight the cost performance category at 20 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Accordingly, we proposed to establish the weight of the quality performance category for the 2023 and 2024 MIPS payment years. At § 414.1330(b)(4), the percentage points attributed to performance in the quality performance category would comprise 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and at § 414.1330(b)(5), the

percentage points attributed to performance in the quality performance category would comprise 30 percent of a MIPS eligible clinician's final score for the 2024 MIPS payment year and future years.

We noted our belief that being transparent in how both the quality and cost performance category weights would be modified over the next 2 years of the program will allow stakeholders to better plan and anticipate how the performance category scores would be calculated in future for MIPS eligible clinicians, groups, and virtual groups as we incrementally adjust the final score weights for the quality and cost performance categories.

We solicited public comment on the proposals to incrementally reduce the weight of the quality performance category as we incrementally increase the weight of the cost performance category, specifically our proposal to adjust the percentage points attributed to the final score in the quality performance category to be comprised of 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and future years. The following is a summary of public comments received regarding the proposals.

Comment: A few commenters supported our proposal to incrementally reduce the weight of the quality performance category while increasing the weight of the cost performance category in order to achieve the weights established by Congress under the Act.

Response: We appreciate the support from commenters.

Comment: Many commenters did not support our proposal to incrementally reduce the weight of the quality performance category in order to increase the weight of the cost performance category during the PHE for COVID–19 because clinicians are burdened in new ways and trying to navigate through various challenges brought on by the PHE. The commenters recommended that CMS maintain the weight of the quality performance category at 45 percent until the PHE for COVID–19 has ended in order for clinicians to focus on serving patients safely. A few commenters recommended that CMS maintain the weight of 45 percent for the quality performance category for the 2023 MIPS payment year in order for the commenters' concerns regarding the cost measures to be addressed. In particular, the commenters noted that there are not many cost measures to select, particularly for specialties, which has significant implications for not accurately measuring cost performance. One commenter requested that CMS work with Congress on an extension for the timeframe to increase the weight for the cost performance category.

Response: Section 1848(q)(5)(E)(i) of the Act provides that by the sixth year of the program, 30 percent of the final score shall be based on performance for the quality performance category and 30 percent of the final score shall be based on the cost performance category. Prior to the sixth year, section 1848(q)(5)(E)(II)(bb) of the Act states that the cost performance category may be weighted at not less than 10 percent and not more than 30 percent of the total score. If less than 30 percent, the percentage by which it is less than 30 percent is to be shifted to the quality performance category. Given that the percentage points attributed to both the quality and cost performance categories are in tandem, and we are required to achieve equal weighting at 30 percent for each of the two performance categories by payment year 2024, we believe that it is important to meet the statutory requirement while balancing the impact of simultaneously reducing the weight of the quality performance category and increasing the weight of the cost performance category. We are providing a gradual transition over a 2-year period subject to the limitations imposed by the statute. In section IV.A.3.c.(2)(a) of this final rule, we finalized our proposal to increase the weight of the cost performance category to 20 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Thus, the weight of the quality performance category will be reduced to 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent years.

Regarding concerns that the weight of the quality performance category should not be reduced until there are additional cost measures applicable to specialties in order to adequately measure cost performance for specialties, we note that there are two broad-based cost measures (Medicare Spending Per Beneficiary Clinician and Total Per Capita Cost) that generally apply to all clinician types, including specialties. There are a total of 20 cost measures, including 18 episode-based cost measures. In the event that there are not any applicable cost measures to measure performance, the cost performance category would be re-weighted to zero. Also, we previously established facility-based measurement. Facility-based measurement provides certain clinicians and groups that primarily work within an inpatient setting with the opportunity to receive MIPS quality and cost performance category scores based on their assigned facility's hospital value-based purchasing program score in lieu of receiving scores based on quality and cost measures. We do not believe that maintaining the weight of the quality performance category at 45 percent until there are additional cost measures is necessary to assess cost performance. We will consider the inclusion of additional cost measures in future rulemaking, as available and appropriate. Regarding the comment requesting that CMS work with the Congress to extend the timeframe for increasing the weight of the cost performance category, we will take the comment into consideration.

After consideration of the public comments, we are finalizing our proposal, which is as follows: At § 414.1330(b)(4), the percentage points attributed to performance in the quality performance category will comprise 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and at § 414.1330(b)(5), the percentage points attributed to performance in the quality performance category will comprise 30 percent of a MIPS eligible clinician's final score for the 2024 MIPS payment year and each subsequent year.

(c) Groups and Virtual Groups Reporting via the CMS Web Interface

At § 414.1335(a)(2), the CMS Web Interface measures is a collection type in which groups and virtual groups with 25 or more eligible clinicians are able to report data on a set of pre-determined quality measures. For the 2020 performance periods, the total number of CMS Web Interface measures required to complete reporting on is 10 CMS Web Interface measures (83 FR 59713 through 79715 and 59756). Each CMS Web Interface measure must have complete reporting (no partial reporting) on all 10 measures while quality measures in other collection types require the reporting of fewer measures. The reporting requirements for the CMS Web Interface measures are more stringent than other collection types for the quality performance category, which include reporting on a larger set of measures and a higher data completeness rate. At § 414.1335(a)(1)(i), it is established that groups and virtual groups reporting quality measures using non-CMS Web Interface measures collection types (such as Qualified Registries, Qualified Clinical Data Registries (QCDRs), electronic health records (EHRs), and Medicare Part B claims) are required to report on a minimum of 6 quality

measures, including at least one outcome measure. The data completeness criteria for reporting quality measures for Qualified Registry measures, QCDR measures, EHR measures, and Medicare Part B claims measures has a lower threshold compared to the CMS Web Interface measures. The data completeness criteria for the CMS Web Interface measures requires groups and virtual groups to report on the first 248 consecutively ranked beneficiaries in the sample for each measure (and if the sample of eligible assigned beneficiaries is less than 248, then the group or virtual group must report on 100 percent of assigned beneficiaries), and at least one measure for which there is Medicare patient data (at §§ 414.1335(a)(2) and 414.1340(c)). For the 2020 performance period, the data completeness criteria threshold for Qualified Registry measures, QCDR measures, EHR measures, and Medicare Part B claims measures is 70 percent of the MIPS eligible clinician, group, or virtual group's patients (and applicable Medicare Part B patients for Medicare Part B claims measures) that meet the measure's denominator criteria (at §§ 414.1340(a)(3) and 414.1340(b)(3)). Thus, groups and virtual groups submitting quality data through the CMS Web Interface measures report on a significantly larger number of patients compared to other collection types and such patients are identified in a sample by us (at § 414.1340(c)).

In sections III.G.1.b. and III.G.1.c. of the CY 2021 PFS proposed rule (85 FR 50231 and 50234 through 50235), we discussed the proposal to revise the quality reporting requirements for the Medicare Shared Savings Program to align with the APP framework and make corresponding revisions to the quality performance standard that ACOs must meet in order to be eligible to share in savings under the program. In conjunction with the proposed modifications to the Medicare Shared Savings Program quality reporting requirements, which included a proposal to transition to an APP for ACOs starting with the 2021 performance period, we conducted an assessment of the utilization of the CMS Web Interface measures as a collection type for groups and virtual groups participating in MIPS. As noted above, we recognize that the CMS Web Interface reporting requirements, which include reporting on a larger set of measures and a higher data completeness rate, are more stringent than other collection types available under MIPS.

In assessing the utilization of the CMS Web Interface by groups and virtual groups, there has been a substantial decrease in participation each year since the inception of MIPS in the 2017 performance year. From the 2017 to 2019 performance years, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS Web Interface as a collection type has decreased by approximately 40 percent from the 2017 to 2019 performance years. It is not clear as to why groups and virtual groups are not seeking to participate in MIPS by submitting quality data for CMS Web Interface Measures. There could be various reasons explaining the decrease in CMS Web Interface participation such as MIPS offering several collection types that can be utilized by any individual MIPS eligible clinician, group, or virtual group to meet program requirements; the CMS Web Interface measure reporting requirements may be burdensome compared to other collection types/submission types; the measure set is limited to primary care; groups and virtual groups may have a preference to select their own measures to have performance assessed instead of a pre-determined measure set; or as a result of the CMS Web Interface measures being topped out, it may deter groups and virtual groups from participating because they would not fiscally benefit to be compared and assessed when there is little or no data variation in performance across ACOs, groups, and virtual groups.

Given the above factors, we considered the following two options in our assessment: Continue the utilization of the CMS Web Interface measures solely for groups and virtual groups while ACOs transition to APP participation; or sunset the utilization for the CMS Web Interface measures as a collection type for groups and virtual groups. Groups and virtual groups account for less than 20 percent of organizations utilizing the CMS Web Interface measures while ACOs participating in the Medicare Shared Savings Program or Next Generation ACO Model account for more than 80 percent. With an expected 80 percent reduction if our proposed revisions to the quality performance standard under the Shared Savings Program are finalized and a continued decrease in groups and virtual groups seeking to report quality data on CMS Web Interface measures, we explained that it is not fiscally viable, feasible, or sustainable for MIPS to continue to make available the CMS Web Interface measures as a collection type/submission type. A reduction in the number of organizations submitting quality data on CMS Web Interface measures does not equate to the reduction in direct costs associated with operating and maintaining the CMS Web Interface measures. To operate and maintain the CMS Web Interface measures solely for groups and virtual groups, there would be an increase in cost and needed resources under MIPS associated with the items such as the establishment and maintenance of CMS Web Interface benchmarks, assignment and sampling, technical support, and education and outreach; thus, there would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface measures as a collection type/submission type.

In assessing the second option to sunset the CMS Web Interface measures as a collection type starting with the 2021 performance year, we would be aligning with the proposal under the Medicare Shared Savings Program to no longer utilize the CMS Web Interface as a means for assessing and scoring the quality performance of ACOs. For purposes of MIPS, groups and virtual groups would transition to meeting requirements under the quality performance category using other collect and submission types. We recognized that the sunset of the CMS Web Interface for groups and virtual groups may be burdensome to current groups and virtual groups submitting quality data on CMS Web Interface measures. Such groups and virtual groups would need to select a different collection type/submission type and redesign their systems to be able to interact with the new collection type/submission type. The timeframe for groups and virtual groups to select a new collection type/submission type and redesign their systems may be perceived as burdensome.

We noted that groups and virtual groups would be able to select a different collection type/submission type, including at least six quality measures that are similar to previously established CMS Web Interface measures and reflect their specialty, and prepare for the 2021 reporting period in advance of the reporting period starting in January of 2022. While there may be an initial increase in burden for current groups and virtual groups utilizing the

CMS Web Interface measures having to transition to the utilization of a different collection type/submission type, we recognized that we would also be reducing reporting requirements by no longer requiring groups and virtual groups to have to completely report on all pre-determined 10 CMS Web Interface measures; groups and virtual groups would be able to select their own measures to report, would be reporting data on at least six measures, and data completeness threshold would be 70 percent for each measure, which is a reduction in program requirements compared to completed reporting required for all CMS Web Interface measures. We noted our belief that groups and virtual groups would be able to transition to the utilization of an available alternative collection type for the 2021 performance period. The type of data collected by groups and virtual groups for the 2020 performance period would be able to be captured by one of the available collection types such as an eCQM or MIPS CQM for the 2021 performance period. The 10 CMS Web Interface measures that are required for reporting under the 2020 performance period have an eCQM and MIPS CQM equivalent measure. For the 2021 performance period, there are 10 eCQMs and 9 CQMs that are equivalent to the 10 CMS Web Interface measures. Also, we noted our belief that groups and virtual groups would be able to identify at least 6 equivalent eCQMs or MIPS CQMs (or a combination) that capture the same type of data collected for the measures used in the CMS Web Interface. Also, such transition for groups and virtual groups could potentially be more beneficial. For example, if a measure from a different collection type (for example, MIPS CQMs) meets data completeness but may not meet case minimum, the measure would receive a score of 3; whereas, under the CMS Web Interface, any measure that did not meet reporting requirements would receive a score of 0.

The sunset of the CMS Web Interface measures would reduce burden on groups and virtual groups while aligning program requirements and scoring policies for MIPS and the Medicare Shared Savings Program, and removing CMS Web Interface measures that do not provide a meaningful means of assessing performance across groups, virtual groups, and ACOs. With the CMS Web Interface measures being topped out as noted above, we strive to remove measures that are topped out and establish a set of robust and meaningful measure sets that are available under the other collection types. We noted our belief that the benefits groups and virtual groups would reap from transitioning to the utilization of other collection types starting with the 2021 performance year outweigh the initial disruption that would be experienced when the CMS Web Interface measures would be sunset. Based on our assessment, we proposed at § 414.1325(c)(1) and (2) to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period. Specifically, at § 414.1305, we proposed to modify the definition of the terms collection type and submission type to remove the CMS Web Interface measures as an available option starting with the 2023 MIPS payment year. We proposed to modify the definition of collection type to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the 2019 through 2022 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS Survey; and administrative claims measures. We proposed to revise the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and for the 2019 through 2022 MIPS payment years, the CMS Web Interface.

We solicited public comment on the proposal to sunset the CMS Web Interface as a collection and submission type under MIPS starting with the 2021 performance period. The following is a summary of public comments received regarding the proposal.

Comment: Several commenters generally supported the proposal to sunset the CMS Web Interface as a collection and submission type (with a few commenters expressing support of the proposal based on the condition of having a transition period of at least 1 year) and noted that the removal of the CMS Web Interface would reduce the quantity of quality measures reported, allow groups and virtual groups to select specialty measures, and encourage the use of electronically reported measures rather than the manual abstraction of data using a CMS-created Excel template for uploading quality data.

Response: We appreciate the support from commenters and note that we are finalizing our proposal to remove the CMS Web Interface as a collection and submission type with a 1-year delay. Also, we note that the CMS Web Interface not only has the function of providing for a manual abstraction of data using a CMS-created Excel template for uploading quality data, but allows for the use of an application programming interface (API), which encourages the use of enhanced EHR technology.

Comment: Most commenters did not support the proposal to sunset the CMS Web Interface as a collection and submission type starting with the 2021 performance period, indicating that CMS did not provide adequate notice of the CMS Web Interface being under consideration for elimination and noting that the lack of adequate notice would create a burden for users to be able to successfully transition to the use of a different collection and submission type, which would require a significant amount of time and fiscal resources to build a new health IT infrastructure and workflows, and train staff on the new system. A few commenters indicated that organizations elect to utilize the CMS Web Interface as a cost-effective option for TINs using multiple, disparate EHR systems and the removal of the CMS Web Interface would make it particularly burdensome for such organization to change collection and submission types. One commenter indicated that not all organizations have the resources to transition to a different collection and submission type and doing so would be difficult for small community practices to implement. Most commenters recommended that CMS delay the sunset of CMS Web Interface by one or more years, particularly as clinicians are responding to the PHE for COVID–19 and CMS continues to define the MVP framework, which may necessitate program participants to change collection and submission types again in a few years.

Response: We recognize that the general sentiment of most commenters was not in opposition to the proposal to remove the CMS Web Interface as a collection type and submission, but rather the proposed timeframe for removal, which would be burdensome due to insufficient time to build and integrate new health IT infrastructures and systems, implement workflows, and train staff on new health IT systems while mitigating and responding to the PHE for COVID–19 that has further strained limited fiscal resources. To reduce the burden of transitioning to a new collection and submission type, we are extending the availability of the CMS Web Interface as a collection and submission type for one additional performance period. Thus, we are

modifying our proposal to sunset the CMS Web Interface starting with the 2022 performance period.

Comment: Some commenters indicated that the removal of the CMS Web Interface as a collection and submission type may limit the ability of clinicians to achieve the maximum possible score under the quality performance category. One commenter expressed concern that as APMs migrate to other collection types, the performance rates for benchmarks of other collection types would increase and the performance of non-APM participants may be disadvantaged when compared to the increased benchmarks.

Response: We disagree that the removal of the CMS Web Interface as a collection type would inhibit APM Entities, groups, or virtual groups that formerly utilized the CMS Web Interface from being able to achieve the maximum possible score allotted under the quality performance category or pose a potential disadvantage for non-APM participants that had not previously reported quality data via the CMS Web Interface as APMs that migrate from utilizing the CMS Web Interface to other collection types. It should be noted that the way in which APM Entities (ACOs participating in the Medicare Shared Savings Program or Next Generation ACO Model), groups, and virtual groups are scored relative to the benchmarks established for the CMS Web Interface measures differ from the way in which MIPS eligible clinicians, groups, virtual groups, and APM Entities are scored relative to the benchmarks established for all other quality measures. The deciles for the CMS Web Interface benchmarks are flat (meaning that each decile is stagnant and equally distributed increments equating 100 percent; for example, if a CMS Web Interface user had a performance score of 92 percent, the points achieved would be 9 points) while the deciles for other quality measure benchmarks are based on the distribution of performance (meaning that each decile reflects a specific range of performance distribution in incremental percentages equating to 100; for example, the decile representing the 10 percent of highest performance could have a range of performance from 98 percent to 100 percent, so in order to achieve the maximum points, a MIPS eligible clinician, group, or virtual group would need to have a performance within such range). Performance rates pertaining to the CMS Web Interface measures are not comparable to performance rates pertaining to other quality measures for other collection types and do not provide an indication of how performance would be distributed across the performance curve outside of the CMS Web Interface. In order to achieve the maximum possible score for the quality performance category, a MIPS eligible clinician, group, virtual group, or APM Entity would need to have better performance compared to other clinicians along the distribution curve of performance for a particular measure.

Comment: One commenter suggested that CMS provide CMS Web Interface users with an option to file a hardship exception for transitioning to a new EHR as a collection type, which would reweight the quality and promoting interoperability performance categories to zero to ensure that such clinicians would not be penalized while transitioning to new collection types.

Response: We disagree with the commenter's suggestion that a hardship exception be established for groups or virtual groups utilizing the CMS Web Interface as such users transition to a different collection type. The hardship exemption is a policy established pertaining to specific circumstances such as using decertified EHR technology, insufficient internet connectivity, extreme and uncontrollable circumstances, and the lack of control over CEHRT. We do not believe that the transition to utilizing a different collection type would warrant the establishment of a new hardship exception. The CMS Web Interface will remain as a collection type for the 2021 performance period to provide sufficient time for CMS Web Interface users to prepare to utilize a different collection type starting with the 2022 performance period as the CMS Web Interface will sunset starting with the 2022 performance period.

Comment: One commenter recommended CMS to provide tools to assist with the transition from the CMS Web Interface to other collection types by providing a simple tool for aggregating QRDAIII files from multiple EHR systems into a single QRDAIII or JSON format file for MIPS submission. The commenter acknowledged that CMS has provided open source software for such purpose, but requested that CMS embed the file aggregation process in the MIPS quality submission workflow in order to allow an authorized submitter to choose an upload and submission method for the quality performance category that automatically aggregates multiple QRDAIII files.

Response: We note that groups and virtual groups are required to aggregate data across the group or virtual group in order to meet reporting requirements established at §§ 414.1310(e)(3) and 414.1315(d)(3). We are unable to provide the embedded aggregation tool the commenter is requesting, but will take this into consideration for future enhancements.

After consideration of the public comments, we are finalizing our proposal to remove the CMS Web Interface as a collection and submission type with a 1-year delay. In order to address the potential burden that groups and virtual groups would experience by the removal of the CMS Web Interface as a collection and submission type during the PHE for COVID–19, we believe it is critical to reduce the burden of groups and virtual groups at this juncture and postpone the sunset of the CMS Web Interface to the 2022 performance period. Thus, we are finalizing at § 414.1325(c)(1) and (2) to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 performance period. Specifically, at § 414.1305, we are finalizing our proposal with modification to define the terms collection type and submission type to remove the CMS Web Interface measures as an available option starting with the 2024 MIPS payment year. We are finalizing our proposal with modification to revise the definition of collection type to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the 2019 through 2023 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS Survey; and administrative claims measures. We are finalizing our proposal with modification to revise the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and for the 2019 through 2023 MIPS payment years, the CMS Web Interface.

(d) Selection of MIPS Quality Measures

Previously finalized MIPS quality measures can be found in the CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). Proposed changes to the MIPS quality

measure set as described in Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50412 through 50663) include the following: Addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the 2021 performance period, we proposed a measure set of 206 MIPS quality measures.

The new MIPS quality measures proposed for inclusion in MIPS for the 2021 performance period and future years were found in Table Group A of Appendix 1 of the proposed rule (85 FR 50413 through 50414). For the 2021 performance year, we proposed 2 new administrative claims outcome measures. In addition to the establishment of new individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. The proposed modifications to existing specialty sets and new specialty sets were outlined in Table Group B of Appendix 1 of the proposed rule (85 FR 50415 through 50580). Specialty sets may include: New measures; previously finalized measures with modifications; previously finalized measures with no modifications; the removal of certain previously finalized quality measures; or the addition of existing MIPS quality measures. Note that the specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 6, 2020,[124] we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 5 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2019 PFS final rule, the 2019 Measures Under Consideration list, and provides recommendations to add or remove the current MIPS quality measures from existing specialty sets, or provides recommendations for the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations with which we agreed were proposed in the CY 2021 PFS proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as outlined in Tables Group A and Group B of Appendix 1 of the CY 2021 PFS proposed rule, we refer readers to Table Group C of Appendix 1 of the CY 2021 PFS proposed rule for a list of quality measures and rationales for removal (85 FR 50580 through 50585). For the 2021 performance period, we proposed to remove 14 MIPS quality measures: 2 MIPS quality measures that are extremely topped out; 1 MIPS quality measure that is duplicative to another current quality measure; 1 MIPS quality measure that is duplicative to one of the new proposed MIPS quality measures; 2 MIPS quality measures that do not align with the Meaningful Measures Initiative; 5 MIPS quality measures that are no longer stewarded or maintained; 1 MIPS quality measure that does not meet current clinical guidelines; and 2 MIPS quality measures that are under the topped out lifecycle. We noted that we have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. Also, we noted our belief that the proposal to remove the quality measures outlined in Table Group C would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to remove measures should occur through an iterative process that will include an annual review of the quality measures to determine whether they meet our removal criteria.

Lastly, MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1 of the CY 2021 PFS proposed rule. We proposed substantive changes to 112 MIPS quality measures. On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive measure changes to be proposed and identified through notice-and-comment rulemaking. In the CY 2017 Quality Payment Program final rule (81 FR 77137), we determined that substantive changes to measures (that is, measure specifications, measure title, and domain modifications) would be identified during the rulemaking process while maintenance changes that do not substantively change the intent of the measure (that is, updated diagnosis and procedure codes, definitions, and changes to patient population exclusions) would not be included in the rulemaking process.

We note that changes to measure Q134, Prevention Care and Screening: Screening for Depression and Follow-Up Plan (eCQM Specifications and CMS Web Interface Measure Specifications collection types), specifically the removal of SNOMED codes, were published in the eCQI Resource Center and the Value Set Authority Center (in May of 2018 for the eCQM Specifications) and on the CMS website (in December of 2018 for the CMS Web Interface Measure Specifications). While the current cycle of measure updates to MIPS quality measures is separate from the eCQM annual update process, we inadvertently recognized such update allowed MIPS eligible clinicians to meet performance of a follow-up plan by rescreening the patient who has a positive depression screen with an additional standardized depression screening tool. The change to the measure was continued for CY 2020. As a result, such changes were not identified during the CY 2019 PFS or CY 2020 PFS rulemaking cycles. The changes to measure Q134 (eCQM Specifications and CMS Web Interface Measure Specifications collection types) impact performance periods starting with 2019. For the 2019 and 2020 performance periods, measure Q134 applicable to the eCQM Specifications and CMS Web Interface Measures Specifications will be suppressed from scoring. To adequately capture the substantive changes to measure Q134 (eCQM Specifications and CMS Web Interface Measure Specifications collection types) through rulemaking for the 2021 performance period, we are identifying the substantive changes for this MIPS quality measure as outlined in Table Group D of Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50586 through 50663).

We refer readers to Table Groups A through D of Appendix 1 of this final rule for a summary of public comments received regarding the proposed changes to the MIPS quality measure set for the 2021 performance period and our final decisions.

(e) MIPS Performance Period

(i) Establishing Separate Performance Periods for Administrative Claims Measures Under the Quality Performance Category Beginning With the 2023 MIPS Payment Year

In the CY 2019 PFS final rule (83 FR 59745), we established at § 414.1320(d)(1) that beginning with the 2022 MIPS payment year, the

[124] Listserv messaging was distributed through the Quality Payment Program listserv on January 6, 2020, titled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure and/or Revisions to the Existing Specialty Measure Sets for the 2021 Program Year of Merit-based Incentive Payment System (MIPS).''

performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. We noted that we established a 1-year performance period for measures in the quality performance category because a 1-year performance period would provide statistically larger sample sizes and more accurate and actionable information. As discussed in Table Group A of Appendix 1 of the CY 2021 PFS proposed rule, we proposed to add a new administrative claims measure of risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty. As discussed, this measure was developed and tested using a performance period that was longer than a full calendar year in order to provide larger sample sizes, and more accurate and actionable information. Beginning with the 2021 performance year, this measure would have a 3-year performance period (consecutive 36-month timeframe) that would start on October 1 of the calendar year 3 years prior to the applicable performance year and conclude on September 30 of the calendar year of the applicable performance year, and proceeding with a 3-month numerator assessment period (capturing complication outcomes) followed by a 2-month claims run-out period. For example, the 3-year (36 consecutive months) performance period for this measure would span from October 1, 2018 to September 30, 2021 with a 90-day numerator assessment period followed by a 60-day claims run-out period.

To account for this measure and other future administrative claims measures that may have a performance period differing from 1 full calendar year, we proposed to modify the definition of the performance period for the quality and cost performance categories at § 414.1320(d)(1) to be as follows: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1). We noted that while we have established a single performance period for measures and activities within each performance category in the MIPS program, we have established measure-specific performance periods in other programs, such as in the hospital value-based purchasing program, which includes measures of various performance periods (84 FR 42394 through 42395). We continue to believe that establishing a single performance period for measures requiring the submission of data optimizes operational efficiency for MIPS eligible clinicians, groups, and virtual groups that submit data on such measures. However, administrative claims measures (proposal to add 2 new administrative claims measures found in Table Group A of Appendix 1 of the CY 2021 PFS proposed rule: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate, and Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)); and the proposal to remove the All-Cause Readmission measure found in Table Group C of Appendix 1 (was the only administrative claims-based measure) do not require the submission of data and are calculated by CMS based on administrative data. Thus, we noted our belief that a different performance period should be considered on a measure-by-measure level for administrative claims measures.

We solicited public comment on the proposal to modify the definition of performance period for the quality and cost performance categories that would establish a separate performance period for administrative claims measures under the quality performance category. The following is a summary of the public comments received regarding the proposal.

Comment: One commenter supported the incorporation of a 3-year timeframe for the RSCR following elective primary THA and/or TKA measure because the measure evaluates individuals and groups over a longer timeframe for increased reliability and aligns with the HWR measure. The commenter recommended that CMS allow for a longer performance period for other MIPS measures, where appropriate.

Response: We appreciate the support from the commenter.

Comment: Several commenters expressed concern about the proposal to establish a separate performance period for administrative claims measures under the quality performance category and recommended that the performance period for administrative claims measures under the quality performance category retain a 1-year performance period. The commenters understood the issue surrounding the basis for larger sample sizes, and more accurate and actionable information needed for reliable measurement, but indicated that a 3-year performance period is too long to provide timely, meaningful feedback for MIPS eligible clinicians. The commenters expressed concern that the performance is not representative of the changes in data over 3 consecutive years. One commenter indicated that many small and independent practices would not be able to retroactively report quality measures that require a 3-year performance window. One commenter stated that differing performance periods under the same performance category would cause confusion for clinicians.

Response: We believe that it is important for measures to be developed based on larger sample sizes, and more accurate and actionable information in order to reliably measure quality performance. We disagree with commenters that a 3-year performance period for administrative claims measures under the quality performance category would inhibit timely and meaningful feedback for MIPS eligible clinicians, groups, and virtual groups; MIPS eligible clinicians, groups, and virtual groups will continue to receive annual, confidential performance feedback reports that reflect prior performance. MIPS eligible clinicians, groups, and virtual groups can compare their performance provided in performance feedback to better understand their performance relative to their peers, identify care coordination and quality of care opportunities, and streamline resource use for their attributed patients. The performance period for administrative claims measures would span a 3-year period, in which 2 years of the 3-year period would overlap with the prior measurement period and 1 year would represent new data. While this approach may not capture small improvements in the quality of care, it ensures statistical reliability and therefore, a valid measure result. For example, the proposed new administrative claims measure of risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty would have a 3-year (36 consecutive months) performance period, including elective primary total hip/knee arthroplasty procedures performed between October 1, 2018 to September 30, 2021.

We do not believe that establishing different performance periods specific to administrative claims measures under the quality performance category would cause confusion within the quality performance category while all other quality measures have a full calendar year as a performance period given that differing performance periods only

pertain to administrative claims measures and the submission of data is not required for such measures due to CMS conducting the calculations based on administrative claims data. The introduction of measure-specific performance periods is a concept established in other CMS programs, such as in the hospital value-based purchasing program, which includes measures of various performance periods (84 FR 42393 through 42395). We continue to believe that establishing a single performance period for measures requiring the submission of data optimizes operational efficiency for MIPS eligible clinicians, groups, and virtual groups that submit data on such measures.

After consideration of the public comments, we are finalizing our proposal to define the performance period for the quality and cost performance categories at § 414.1320(d)(1) as follows: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1).

(f) Quality Data Submission Criteria

(i) Performance Criteria for Quality Measures for Groups Electing To Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53629 through 53632) for previous finalized policies for the CAHPS for MIPS Survey, specifically regarding the Summary Survey Measures (SSMs).

To address the PHE for COVID–19 and the increased use of telehealth care, we proposed the following changes to our policies related to the CAHPS for MIPS Survey:

- We proposed to integrate one telehealth item into the CAHPS for MIPS Survey. Specifically, we proposed to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services (for example, phone or video visit) to the PY 2021 CAHPS for MIPS Survey.
- We also proposed revisions to the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings. This may help to ensure that patients who respond to the survey are reflecting on experiences of the care they received via telehealth in their responses. We noted that we are considering such changes for the PY 2021 CAHPS for MIPS Survey administration.
- To clarify the instructions in the CAHPS for MIPS Survey, we proposed revisions to the instructions in the ''Your Care From Specialists in the Last 6 Months'' section of the CAHPS for MIPS Survey to clarify the inclusion of the provider named in Question 1 of the survey. We noted that we are considering such changes for the PY 2021 CAHPS for MIPS Survey administration.

We refer readers to section VII of this rule the Collection of Information Requirements for additional information.

We received public comments on the performance criteria for quality measures for groups electing to report CAHPS for MIPS Survey proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported adding a survey-based measure in the CAHPS for MIPS Survey that reflects the increased use of telehealth services, and helps clinicians understand utilization patterns, consumer satisfaction and outcomes of telehealth. One commenter indicated support for a survey question related to the use of telehealth services only, but not a question or measure to evaluate a clinician's performance during the telehealth visit.

Response: We clarify that the item on use of telehealth would be a single question that collects self-reported information from CAHPS for MIPS Survey respondents on the modalities of care they received over the prior 6 months (in-person, by phone, or video visit). We clarify here that this survey item would be for informational purposes only (similar to the existing CAHPS for MIPS Survey item that assesses internet use at home), and would not be used for quality scoring or payment purposes.

Comment: One commenter did not support the inclusion of a new measure assessing telehealth services until there is clarification on the intent of the questions, descriptions of what information will be collected, robust testing of the usefulness of the new measure and impact on response rates and performance, and NQF endorsement of the new CAHPS for MIPS survey question. One commenter wanted clarification on whether the purpose of adding a telehealth measure is to assess digital literacy of patients or to allow patients to assess the degree to which services provided remotely were appropriate and met their needs.

Response: We note that in 85 FR 50292, we proposed to integrate a single item into the CAHPS for MIPS Survey to collect respondents' self-reported data on use of telehealth services (for example, by phone or video visit) during the prior 6 months. We clarify here that this survey item would be for informational purposes only (similar to the existing CAHPS for MIPS Survey item that assesses internet use at home). That is, this item would not be used for quality scoring or payment purposes. Rather, the purpose of this question would be to provide CMS and participating groups with useful information about utilization of telehealth by their assigned patients, specifically, self-reported data on mode of telehealth delivery (phone vs. video). The item will also capture whether any in-person visits occurred and will allow CMS and participating groups to examine the reports and ratings of care for patients receiving telehealth visits and will allow CMS to examine resulting CAHPS scores for groups whose patients used telehealth. It may promote comparison of the experiences of patients using telehealth with those who have not used telehealth, which could inform quality improvement efforts for individual groups and allow CMS to monitor the experiences of assigned patients (both those utilizing telehealth and those who do not). The proposed item has not been field tested. As with existing CAHPS for MIPS Survey items, the proposed item has been tested in one-on-one interviews with patients to assess whether patients correctly understand the terms and phrases used in the question and are able to recall experiences relevant to the question. Testing was conducted in English and Spanish. CAHPS for MIPS Survey items are not a candidate for NQF review. We do not anticipate the addition of a single telehealth question will affect the survey response rate. Given the rapidly evolving use of telehealth services as a result of the COVID–19 pandemic, we believe the addition of an item to capture the use of telehealth should be added to the performance year 2021 CAHPS for MIPS Survey.

Comment: A few commenters supported the proposed revisions to the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings.

Response: We appreciate the commenters for their support.

After consideration of public comments, we are finalizing our proposal to integrate one telehealth item and update the cover page to reference to care received in telehealth settings

starting in the PY 2021 CAHPS for MIPS Survey administration. Additionally, while no public comments were received, as a result of the qualitative testing we are not making any changes regarding the instructions in the ''Your Care From Specialists in the Last 6 Months'' section of the CAHPS for MIPS Survey in Question 1 of the survey.

(ii) CAHPS for MIPS Patient Assignment

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, these specified Medicare telehealth services are reported using the same codes used for the ''face-to-face'' services, but are furnished using audio/video, real-time, interactive communications technology instead of in person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID–19 IFC for purposes of the PHE for COVID–19 are already included in the definition of primary care services for purposes of the MIPS assignment methodology for the CAHPS for MIPS Survey (82 FR 77168 through 77169; and 82 FR 53646 through 53647). At § 414.1305, we proposed to codify the definition of primary care services for purposes of MIPS assignment methodology for the CAHPS for MIPS Survey as follows:

• CPT codes:

++ 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for E/M services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

++ Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital E/M services (e-visit)); 99441, 99442, and 99443 (codes for telephone E/M services); and 96160 and 96161 (codes for Administration of Health Risk Assessment).

• HCPCS codes:

++ G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

++ Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

In the March 31st COVID–19 IFC, we also established flexibilities for certain services that are furnished virtually using communication technologies, but that are not considered Medicare telehealth services such as virtual check-ins and e-visits (separate payments for such services had previously been established in the CY 2019 PFS final rule). We also established separate payment for telephone E/M services codes during the PHE. The communications technology-based services (CTBS) and the telephone E/M services are not currently included in the MIPS assignment methodology for the CAHPS for MIPS survey.

We believe it is critical to include codes for CTBS and telephone E/M services, as identified and discussed later in this section, in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment. Such inclusion ensures that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for COVID–19 and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth or other uses of communications technology, we would ensure that this care is appropriately reflected in our consideration of the plurality of care used to assign beneficiaries to groups and virtual groups.

We have added new services to the separately billable CTBS under the Physician Fee Schedule over the past several years and a result of the PHE, we expect that the utilization of communications technology-based services will substantially increase during the PHE for COVID–19 and thereafter. We believe that clinicians are increasingly using such services as a key component of their ongoing primary care. In an effort to address the increased use of telehealth during the PHE and use of telehealth, and to maintain alignment with the Shared Savings Program, we proposed to integrate the same telehealth CPT and HCPCS codes that are used for purposes of assigning beneficiaries to Shared Savings Program ACOs into the set of primary care service codes that are used for patient assignment to MIPS groups. We proposed to revise the definition of primary care services used in the MIPS assignment methodology for the 2021 CAHPS for MIPS Survey, and for any subsequent performance year, to include the following additions: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M services (e-visits)); 99441, 99442, and 99443 (codes for telephone E/M services); and 96160 and 96161 (codes for administration of health risk assessment); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). It should be noted that the proposed inclusion of such codes in the MIPS assignment methodology for the CAHPS for MIPS Survey would align with the definition of primary care services used for purposes of beneficiary assignment under the Medicare Shared Savings Program, which was amended in the May 8th COVID–19 IFC to ensure that these codes for e-visits, telephone E/M services, remote evaluation of patient video/images, and virtual check-ins would be included in determining beneficiary assignment for the 2020 performance year and any subsequent performance year that starts during the PHE for COVID–19 (85 FR 27583). We referred readers to the May 8th COVID–19 IFC (85 FR 27582 through 27586) for a detailed description of the codes that were added to the definition of primary care services under the Medicare Shared Savings Program. We also referred readers to the 2018 PFS final rule (82 FR 53007 through 53011) for a detailed description of the primary care services codes for Administration of Health Risk Assessment.

The services represented by the codes listed above are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We noted that as a result, we believe these services are an important component of primary care and it is appropriate to include these codes in the definition of primary care services used for assignment for the CAHPS for MIPS Survey. The only codes that are newly billable during the PHE for COVID–19 pertain to the telephone E/M services. It should be noted that these services as well as the remote evaluation of patient video/images and virtual check-in codes, and the online digital E/M service (e-visit) codes are not separately billable by a clinician if they are related to a visit within the past 7 days or lead

to a visit within the following 24 hours or next available appointment.

We believe that clinicians are increasingly using CTBS as a key component of their ongoing primary care. We noted that we expect that the utilization of such services will substantially increase not only during the PHE for COVID–19, but also thereafter. Accordingly, we proposed to include virtual primary care visits and telehealth visits to determine patient assignment to groups for purposes of the CAHPS for MIPS Survey for PY 2021 and subsequent performance years.

We did not receive public comments on this proposal, and therefore, we are finalizing it as proposed.

(g) Quality Performance Category: Expansion of Telehealth Codes Used in Beneficiary Assignment for the CMS Web Interface and CAHPS for MIPS Survey

(i) Background

In conjunction with this final rule and the ongoing impact of the PHE for COVID–19, we published the ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' IFC in the September 2, 2020 **Federal Register**, (hereinafter referred to as the September 2nd COVID–19 IFC), in which we adopted on an interim final basis a policy to include codes for CTBS and telephone E/M services in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment.

As discussed in the IFC, on March 17, 2020, we announced (*https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet*) the expansion of payment for telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 such that Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence, starting March 6, 2020. In the context of the PHE for COVID–19, we recognize that physicians and other health care professionals are faced with new challenges regarding potential exposure risks, including for Medicare beneficiaries, for health care providers, and for members of the community at large. For example, the CDC has recommended health care professionals to make every effort to interview persons under investigation for infection by telephone, text messaging system, or video conference instead of in-person. In the March 31st COVID–19 IFC, to facilitate the use of telecommunications technology as a safe substitute for in-person services, we added on an interim basis many services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks (85 FR 19232).

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, these specified Medicare telehealth services are reported using the same codes used for the ''face-to-face'' services, but are furnished using audio/video, real-time, interactive communications technology instead of in person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID–19 IFC for purposes of the PHE for COVID–19 are already included in the definition of primary care services for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey (81 FR 77168 through 77169; and 82 FR 53646 through 53647).

In the March 31st COVID–19 IFC, we also established flexibilities and separate payment for certain services that are furnished virtually using communication technologies, but that are not considered Medicare telehealth services such as virtual check-ins, e-visits. Additionally, we established separate payment for telephone E/M services codes during the PHE. The CTBS and the telephone E/M services are not currently included in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey.

We believe it is critical to include codes for CTBS and telephone E/M services, as identified and discussed later in this section, in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment. Such inclusion ensures that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for COVID–19 and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth, or other uses of communications technology, we ensure that this care is appropriately reflected in our consideration of the plurality of care used to assign beneficiaries to groups and virtual groups.

(ii) Use of Codes for Virtual Check-ins, Remote Evaluations E-Visits, and Telephone E/M Services in MIPS Beneficiary Assignment for the CMS Web Interface and CAHPS for MIPS Survey

We added new services to the separately billable CTBS under the PFS over the past several years and a result of the PHE for COVID–19, we expect that the utilization of CTBS will substantially increase during the PHE for the COVID–19 pandemic and thereafter. We believe that clinicians are increasingly using such services as a key component of their ongoing primary care. In the September 2nd COVID–19 IFC (85 FR 54820), we codified the definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey. The included codes consisted of previously finalized codes that were already considered primary care services and additional codes that we will be treating as primary care services for the duration of the PHE for COVID–19. The previously finalized codes were as follows: (1) CPT codes: 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31) (81 FR 77168); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for E/M services furnished in a patients' home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for

chronic care management); and 99495 and 99496 (codes for transitional care management services); and (2) HCPCS codes: G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits). The additional codes we added through the September 2nd COVID–19 IFC are as follows: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). It should be noted that the inclusion of such codes for the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey aligns with the revision that was made to the definition of primary care services used for purposes of beneficiary assignment under the Medicare Shared Savings Program to include the same codes in determining beneficiary assignment for performance year 2020 and any subsequent performance year that starts during the PHE for COVID–19 (85 FR 27583 through 27586).

The services listed above are an important component of primary care and as a result, we believe it is appropriate to include these codes in the definition of primary care services used for assignment for the CMS Web Interface and CAHPS for MIPS Survey because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. It should be noted that the remote evaluation of patient video/images and virtual check-in codes, and the online digital E/M service (e-visit) codes are not separately billable by a clinician if they are related to a visit within the past 7 days or lead to a visit within the following 24 hours or next available appointment. The only codes that are newly billable during the PHE for COVID–19 pertain to the telephone E/M services.

We included the codes in the definition of primary care services for the 2020 performance year and any subsequent performance year that starts during the PHE for COVID–19. We recognized that the application of this policy for the 2020 MIPS performance period is retroactive. Section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. Without the inclusion of these codes for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey for the 2020 performance year during the PHE for COVID–19, we would not be able to adequately account for the ways in which beneficiaries are receiving primary care services during the PHE for COVID–19 and as a result, the process to derive assignment and sampling of beneficiaries for the CMS Web Interface and CAHPS for MIPS Survey would not be able to comprehensively capture how primary care services are being furnished to beneficiaries, which may cause many groups and virtual groups to have insufficient sample sizes to be able to administer the 2020 CAHPS for MIPS Survey or report data for the quality performance category using the CMS Web Interface measures. In regard to the CMS Web Interface, such groups and virtual groups may not have sufficient time to select an alternate collection type and prepare their systems to report on measures from a different collection type before the submission period begins for the 2020 performance period and as a result, they would not be able to meet the quality performance category reporting requirements, which could negatively impact their MIPS final score and MIPS payment adjustment. We believe it is important to include the above codes in our assignment methodology because we determine assignment based upon where beneficiaries receive the plurality of their primary care services and whether beneficiaries have designated a MIPS eligible clinician as their primary clinician, responsible for their overall care, and hold groups and virtual groups accountable for the resulting assigned beneficiary population. Including such codes in the definition of primary care services used in MIPS beneficiary assignment during the PHE for COVID–19 will result in a more accurate identification of where beneficiaries have received the plurality of their primary care services.

We received the following comments on the codified definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey.

Comment: Several commenters supported the proposal to expand the use of telehealth codes to the definition of primary care services that is used in the beneficiary assignment for purposes of MIPS for the CMS Web Interface and CAHPS for MIPS Survey. The commenters indicated that the inclusion of CTBS and telephone E/M services in the primary care definition appropriately reflects the reality of the care being provided during the PHE for COVID–19 and allows patients with mild symptoms to remain in their homes while maintaining access to care. Some commenters stated that the expansion of CTBS and telephone E/M services codes may incentivize clinical data registry reporting. A few commenters recommended that CMS continue this policy on a permanent basis.

Response: We appreciate the support from commenters. In regard to the comment about the applicability of including the added CTBS and telephone E/M services codes for purposes of the assignment methodology on a permanent basis, we note that for purposes of the CMS Web Interface, the addition of such codes would be included for the 2020 performance year and any subsequent performance year that starts during the PHE for COVID–19. The CMS Web Interface will be removed as a collection and submission type starting with the 2022 performance period. For purposes of the CAHPS for MIPS Survey, in section IV.A.3.c.(1)(f)(ii) of this final rule, we note that the inclusion of the added CBTS and telephone E/M services codes in the assignment methodology would be applicable for PY 2021 and subsequent performance years.

Comment: One commenter requested that CMS consider the inclusion of audio-only services.

Response: We will take into consideration the inclusion of other additional service codes pertaining to telehealth services for future rulemaking.

After consideration of the public comments, we are finalizing the provisions of the September 2nd COVID–19 IFC without any modifications. We are finalizing the codified definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey for the 2020 performance year due to the PHE for COVID–19 as defined in § 400.200, to include the following additions: (1) CPT codes: 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31) (81 FR 77168); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for E/M services furnished in a patients' home for claims identified by POS modifier

12); 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and (2) HCPCS codes: G0402 (code for the Welcome to Medicare visit); G0438 and G0439 (codes for the annual wellness visits); G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

(2) Cost Performance Category

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 and CY 2020 PFS final rules (81 FR 77162 through 77177, 82 FR 53641 through 53648, 83 FR 59765 through 59776, and 84 FR 62959 through 62968, respectively) for a description of the statutory basis and existing policies pertaining to the cost performance category.

In the CY 2021 PFS proposed rule (85 FR 50293), we proposed to weight the cost performance category at 20 percent for MIPS payment year 2023 and 30 percent for MIPS payment year 2024 and all subsequent MIPS payment years.

(a) Weight in the Final Score

Under section 1848(q)(5)(E)(i)(II)(aa) of the Act, in general, 30 percent of the MIPS final score shall be based on the cost performance category. However, section 1848(q)(5)(E)(i)(II)(bb) of the Act gives the Secretary discretion with respect to the weight of the cost performance category for the first 5 years of MIPS. Specifically, under that section, for the first year for which the MIPS applies to payments (the 2019 MIPS payment year), not more than 10 percent of the MIPS final score shall be based on the cost performance category; and for each of the second, third, fourth, and fifth years for which the MIPS applies to payments (the 2020, 2021, 2022, and 2023 MIPS payment years, respectively), not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category. Additionally, section 1848(q)(5)(E)(i)(II)(bb) of the Act states that it shall not be construed as preventing the Secretary from adopting a 30 percent weight for the second, third, fourth, or fifth year if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period. The weights adopted in prior rulemaking for the cost performance category are codified under § 414.1350(d).

In the CY 2020 PFS proposed rule (84 FR 40752), we proposed to incrementally increase the weight of the cost performance category from the existing weight of 15 percent for the 2021 MIPS payment year to 30 percent beginning with the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. We proposed to incrementally increase the weight of the cost performance category by 5 standard increments each year through the 2024 MIPS payment year, reflecting a weight of 20 percent for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year (84 FR 40752 through 40753).

As cost measures are still being developed, we recognized that clinicians may not have the same level of familiarity or understanding of cost measures as they do with the comparable quality measures. To implement a gradual and predictable approach of increasing the weight of the cost performance category each year would provide clinicians with adequate time to prepare for a 30 percent weight and enable clinicians to gain experience with the cost measures while they represent a smaller portion of the MIPS final score. We recognized that there may be greater understanding of the measures in the cost performance category as clinicians obtain more experience with the measures (84 FR 62959).

After considering the comments we received, we did not finalize our proposals, and instead established at § 414.1350(d)(3) that the weight of the cost performance category will remain at 15 percent of the MIPS final score for MIPS payment years 2021 and 2022 (84 FR 62961). We stated that we expected to propose a weight for the cost performance category for the 2023 MIPS payment year in the CY 2021 PFS proposed rule.

In developing the proposals in the CY 2021 PFS proposed rule, we considered a range of numerical options for the weight of the cost performance category for the 2023 MIPS payment year, with the intention of reaching a weight of 30 percent no later than the 2024 MIPS payment year as required by the statute. The first option we considered was to maintain the cost performance category weight at the status quo for an additional year, in which it would remain at 15 percent for the 2023 MIPS payment year and then increase to 30 percent beginning with the 2024 MIPS payment year, which would be a 100 percent increase (an increase of 15 percentage points) in the weight from 2023 to 2024. We considered such option as a result of the PHE for COVID–19 in order to not increase the weight of the cost performance category during an unprecedented time. However, by maintaining the weight at 15 percent for the 2023 MIPS payment year, the weight would increase two-fold to 30 percent beginning with the 2024 MIPS payment year, which we believe would pose a significant burden to stakeholders and would eliminate any transition of an incremental increase in the cost performance category weight. We believe that the first option would be more burdensome than beneficial to clinicians as they continue to gain more experience with the cost measures and confront the PHE for COVID–19.

The second option we considered was to increase the weight from 15 percent for MIPS payment years 2021 and 2022 to 20 percent for the 2023 MIPS payment year in order to provide a minimal transition that would enable clinicians to continue to become familiar with the cost measures and be prepared for the final increase in the weight of the cost performance category from 20 percent to 30 percent beginning with the 2024 MIPS payment year. We believe that such approach would allow us to reach the statutorily required weight of 30 percent by the 2024 MIPS payment year while providing clinicians with an eased incremental transition starting with the 2023 MIPS payment year and accounting for the consequential impact of the increased clinical costs associated with the PHE for COVID–19. For the 2023 MIPS payment year, we sought to identify a smaller increase in weight while enabling clinicians to gain more experience and familiarity with the cost measures amidst the mitigation of the PHE for COVID–19.

After considering these options, we proposed to establish at § 414.1350(d)(4) the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and at § 414.1350(d)(5) the weight of the cost performance category to be 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year.

We solicited public comment on the proposal, the other options we considered, and any additional options for the weight of the cost performance category that commenters believe we should consider, such as a 22.5 percent weight for the 2023 MIPS payment year and a 30 percent weight beginning with the 2024 MIPS payment year (a 7.5 percent increase for each year). In

general, we noted that we prefer to consider whole numbers for performance category weights, but were interested in obtaining feedback from commenters on the weighing of the cost performance category to have an increase of 7.5 percent for 2 consecutive years for the 2023 and 2024 MIPS payment years.

The following is a summary of the public comments received regarding the proposal to establish the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and 30 percent of the MIPS final score for the 2024 MIPS payment year and each subsequent MIPS payment year and other options for weighting the cost performance category.

Comment: Several commenters supported the proposal to reduce the weight of the quality performance category while simultaneously increasing the weight of the cost performance category. Some commenters supported a gradual and incremental weight increase of the cost performance category from 20 percent for the 2023 MIPS payment year to 30 percent for the 2024 MIPS payment year as a means to balance short-term scoring changes with long-term statutory requirements, which would enable MIPS eligible clinicians, groups, and virtual groups to continue to become familiar with cost measures and be prepared for the final weight increase to 30 percent for the 2024 MIPS payment year. One commenter indicated that such increases to the weight of the cost performance category have been anticipated and is statutorily mandated. Another commenter indicated that the changes to the weight of the cost performance category would heighten the importance of efficiency and cost control for clinicians remaining in FFS and encourage more clinicians to consider migrating to APMs. Another commenter stated that the gradual and incremental increase in weighting for the cost performance category would help compensate for the impact of increased clinical costs associated with the PHE for COVID–19.

Response: We appreciate the support from commenters and agree that providing a 2-year timeframe for the cost performance category to gradually increase would allow us to meet the statutory requirement for weighing the cost performance category at 30 percent by the 2024 MIPS payment year. We also agree that this approach of gradually and incrementally increasing the weight of cost enables MIPS eligible clinicians, groups, and virtual groups to continue to become familiar with the cost measures during the PHE for COVID–19.

Comment: In regard to other options for weighing the cost performance category, one commenter indicated that a 7.5 percent increase in weight each year over a 2-year period (22.5 percent for the 2023 MIPS payment year and 30 percent for 2024 MIPS payment year) may be the most equal option, but that a 5-percentage point weight increase from 15 percent to 20 percent for the 2023 MIPS payment year and a 10-percentage point weight increase from 20 percent to 30 percent for the 2024 MIPS payment year would not be any more of a burden. Another commenter recommended that the weight of the cost performance category be weighted in whole numbers.

Response: We recognize that any increase in weight for the cost performance category could potentially pose varying levels of burden; however, we sought to decrease burden by establishing a gradual and incremental transition over a 2-year period while allowing clinicians to gain more experience with the cost measures and confront the challenges brought forth by the PHE for COVID–19. We believe that increasing the weight of the cost performance category from 15 percent to 20 percent for the 2023 MIPS payment year in order to provide a minimal transition would enable clinicians to continue to become familiar with the cost measures and be prepared for the final increase in the weight of the cost performance category from 20 percent to 30 percent beginning with the 2024 MIPS payment year, which allows clinicians to become familiar with cost measures and accounts for the consequential impact of the increased clinical costs associated with the PHE for COVID–19. In regard to the comment pertaining to the weight of the cost performance category to be in whole numbers, we agree with the commenter that weighting the cost performance category in whole numbers may reduce added confusion and complexity within our scoring system.

Comment: A few commenters suggested that as the weight of the cost category increases, CMS should help clinicians understand their performance throughout the performance period by creating an application programming interface (API) or another mechanism to provide MIPS eligible clinicians, groups, and virtual groups with real-time information about their cost score in order for them to understand their performance during the performance year and identify areas for improvement.

Response: We appreciate the recommendation from the commenters. We strive to provide performance feedback reports on the MIPS performance categories as soon as we are able to technically and feasibly do so. In order to further assist MIPS eligible clinicians, groups, and virtual groups in understanding their performance under the cost performance category, we provide additional feedback on cost measures that is at the patient level. With the submission and analysis of all data, including the assessment and calculation of cost data occurring after the conclusion of the applicable performance year, it would be impossible to provide real-time scores and feedback reports when the cost performance category has a performance period of a full calendar year, in which performance is based on 12 months of data. We believe that MIPS eligible clinicians, groups, and virtual groups are able to benefit and effectively utilize the performance feedback reports that are typically available around July 1 after the close of the submission period for an applicable performance period. Information provided in the feedback reports are applicable and can be used by MIPS eligible clinicians, groups, and virtual groups to identify areas for improvement for the cost performance category.

Comment: Many commenters did not support the proposal to reduce the weight of the quality performance category to increase the weight of the cost performance category during the PHE for COVID–19 given clinicians are burdened in new ways and trying to navigate through various challenges brought on by the PHE. Several commenters indicated that the PHE for COVID–19 has caused major disruptions in practice, prompting the need to adjust to unusual and unpredictable patient volumes, and indicated that the PHE would impact performance data and therefore, the ability of CMS to accurately assess quality and cost. One commenter indicated that practices in COVID–19 hotspots that are testing for and treating patients with the virus, and fighting the pandemic would be unfairly penalized. Several commenters urged CMS to defer changes to the weight of the cost performance category and maintain the weight at 15 percent of the final MIPS score for the 2023 MIPS payment year while a few commenters recommended that the cost performance category be reweighted to zero percent for the 2023 MIPS payment year to provide clinicians with more time to care for patients through the pandemic, as well as familiarize themselves with

their resource use, including telehealth visits.

Other commenters expressed concern regarding the appropriateness of the cost measures, specifically indicating that there are not many cost measures available to assess cost performance, particularly for specialties. These commenters indicated that a limited number of cost measures would have significant implications for not accurately measuring cost performance and requested that we add new cost episodic-based measures for specialties. One commenter expressed concern that the outcome measures for many specialties are still in the testing phase and indicated that there continues to be confusion surrounding their use and reliability. These commenters did not support any increases to the weight of the cost performance category until more cost measures are available and concerns regarding the validity and accuracy of existing cost measures are addressed (for example, attributing costs at the group level (not attributing the same costs to both individual clinicians and groups), adjusting for risk of social determinants of health, publishing detailed testing results, and holding all measures to strict standards for reliability, statistical significance, actionability, and impact on health outcomes).

Response: Under section 1848(q)(5)(E)(i)(I) and (II) of the Act, for each of the first 5 years of MIPS, the weight of the quality performance category in the final score is determined based on the weight of the cost performance category. The statute requires that by the sixth year of MIPS, the quality performance category and the cost performance category each will make up 30 percent of the final score. Given that the percentage points attributed to the quality and cost performance categories are in tandem, we believe that it is important to meet the statutory requirements while balancing the impact of simultaneously reducing the weight of the quality performance category and increasing the weight of the cost performance category. We believe that increasing the weight of the cost performance category to 20 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year provides a transition that eases the impact of experiencing an increase in the weight of the cost performance category by enabling a gradual and incremental transition over a 2-year period while clinicians confront the challenges brought forth by the PHE for COVID–19 and become familiar with cost measures and feedback reports.

In regard to concerns regarding an insufficient number of cost measures for specialties, and the appropriateness, actionability, validity, and accuracy of available cost measures, we recognize that measures focusing on specific clinical areas and specialties allow for clinicians to receive more actionable and meaningful feedback. To date, we have developed and implemented 18 episode-based cost measures, which are intended to capture the nuances of costs associated with procedures and conditions spanning different types of specialties and clinical areas. We revised the total per capita cost measure to focus on specialties that provide primary care and the Medicare spending per beneficiary clinician measure to focus on costs associated with an inpatient hospitalization. We anticipate that future measures may apply to a greater range of specialties and clinical areas, including areas suggested by stakeholders. We believe that we are able to continue to accurately assess performance for the cost performance category with the available cost measures; in the event that we cannot calculate a score for a given cost measure (for example, if we cannot calculate a benchmark for the measure, or a clinician does not meet the minimum case volume), the measure will not be scored and thus will not affect a clinician's overall cost performance category score. It should be noted that we are not able to address concerns with the existing cost measures during this rulemaking cycle for 2021 performance year given that any new cost measure or modifications to the existing cost measures for the 2021 performance period would have had to be proposed in the CY 2021 PFS proposed rule. The next opportunity for us to introduce new cost measures or modify existing measures would be for the 2022 performance year rulemaking cycle. We do not believe that maintaining the weight of the cost performance category at 15 percent until there are additional cost measures or modifications made to cost measures would be appropriate as we are statutorily required to increase the weight of the cost performance category to 30 percent by the 2024 MIPS payment year and want to ease the impact of experiencing the increase in the weight of the cost performance category by providing a gradual and incremental transition over a 2-year period. We believe it would be significantly more burdensome for MIPS eligible clinicians, groups, and virtual groups to experience a two-fold increase from 15 percent to 30 percent beginning with the 2024 MIPS payment year.

In regard to the concerns about inaccurately assessing cost performance amidst the PHE for COVID–19 and unfairly penalizing practices in COVID–19 hotspots that are testing for and treating patients with the virus, and fighting the pandemic, we note that service assignment allows the episode-based cost measures to capture only the cost of services that are clinically related to the triggering event for the episode (for example, a knee replacement procedure or a hospitalization for stroke). This means that costs resulting from high volumes of COVID–19 treatment services are less likely to be captured in the episode-based costs measures. In addition, all cost measures, including total per capita cost measure and Medicare spending per beneficiary clinician measure are adjusted for clinical risk to account for different levels of care beneficiaries may require due to comorbidities, disability, age, and other risk factors. The risk adjustment model includes variables for clinical factors based on the patient's recent medical history that are outside the influence of the attributed condition to ensure that clinicians who treat higher risk populations, are not penalized. Also, cost measures use standardized claims payments to account for differences in Medicare payments for the same services across health care providers, removing the effect of regional differences in health care provider costs measured by the hospital wage indexes and geographic price cost indexes (GPCIs) or other payment adjustments such as those for teaching hospitals. The payment standardization process also removes the 20 percent increase in the IPPS relative weight under the CARES Act for individuals diagnosed with COVID–19. Furthermore, we have policies in place to account for scenarios when we cannot calculate a score for a given cost measure that does not meet our reliability and benchmark requirements. We believe that the measures in place will allow us to continue to accurately assess cost performance.

In regard to the comment expressing concern about outcome measures for specialties, we note that we have not adopted any such measures in the cost performance category, as these are quality measures. The episode-based cost measures pertaining to specialties that we have adopted are procedural and acute inpatient medical condition measures. These measures focus on the clinicians performing particular procedures or managing particular acute

inpatient medical conditions. These clinicians may often come from one specialty, but not necessarily.

After consideration of the public comments, we are finalizing our proposal to establish at § 414.1350(d)(4) the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and at § 414.1350(d)(5) the weight of the cost performance category to be 30 percent of the MIPS final score for the 2024 MIPS payment year and each subsequent MIPS payment year. We believe that such approach allows us to reach the statutorily required weight of 30 percent by the 2024 MIPS payment year while reducing the impact of experiencing an increase in the weight of the cost performance category too much in any one year, and providing clinicians with an eased gradual and incremental transition starting with the 2023 MIPS payment year.

(b) Addition of New Codes for Telehealth Services to Previously Established Measures for the Cost Performance Category Beginning With the 2021 Performance Period

For the 2021 performance period and future performance periods, we proposed to add costs associated with certain telehealth services to the previously established cost measures. For each cost measure, the telehealth services we proposed to add are directly relevant to the intent of the measure. We referred readers to Table 47 in the CY 2020 PFS final rule (84 FR 62979) for a summary list of the cost measures that have been established for the 2021 performance period and future performance periods, as well as the related discussions in the CY 2019 PFS final rule (83 FR 59767 through 83 FR 59774) and the CY 2020 PFS final rule (84 FR 62962 through 62979). Many services included on the Medicare telehealth service list are billed as telehealth services through the use of a modifier appended to the same code that is used when the service is furnished in person. These codes are already included in the cost measures; however, the additional codes we proposed to add are not currently included for a few reasons. First, some of the codes we proposed to add to the cost measures were newly included on the Medicare telehealth services list through the March 31st COVID–19 IFC (85 FR 19230) and subsequent subregulatory process established in the May 8th COVID–19 IFC (85 FR 27550). Second, some of the codes we proposed to add were not previously considered for inclusion because they were not billed widely enough to be found in empirical claims-based data. This is because our approach for determining clinically related services to include in cost measures, which we established in the CY 2019 PFS final rule (83 PFS 59767 through 59771), relies on empirical data to examine existing practice patterns, in addition to clinical expertise. Having observed an increase in the use of these codes, including those that existed before the PHE for COVID–19, we proposed to add them to adapt the measures to this change in practice patterns. The codes we proposed to add to the cost measures represent service categories already captured in the measures (for example, E/M, follow up consultation following hospital discharge); thus, we do not consider their addition to alter the intent of the measures or capture a new category of costs. Updated measure specifications with the added telehealth codes are available on the CMS website at *http://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*.

We solicited public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to add costs associated with certain telehealth services to the previously established cost measures beginning with the 2021 performance period. Other commenters requested that CMS release updated measure specifications that include the additional telehealth services as soon as possible.

Response: We appreciate the support of our proposal to add costs associated with certain telehealth services to the cost measures. We posted the measure codes list files, which include the telehealth codes that we proposed to add for each cost measure, at the link specified in the proposed rule (*http://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*) (85 FR 50294) for the duration of the public comment period.

Comment: One commenter suggested that CMS explore options for separately identifying telehealth services on episode cost performance feedback reports provided to clinicians to help guide clinicians' assessment of optimal telehealth use from the cost perspective.

Response: We thank the commenter for their suggestion. We will explore the possibility of including information on telehealth use when producing future performance feedback reports.

Comment: A few commenters suggested that CMS conduct and publicly share testing on the inclusion of telehealth services in the existing cost measures so that clinicians can become more familiar with how these services will affect the measures and to allow CMS to implement any necessary changes based on input from physician specialty societies regarding the impact of the addition of these services. One commenter indicated that the codes CMS proposed to add within the cost measures represent service categories already captured in the measures and requested that CMS clarify whether they plan to alter the intent of the cost measures. Another commenter requested more information on how telehealth services would be identified, whether the inclusion of these services could penalize physicians practicing in areas with COVID–19 outbreaks, and whether there will be downstream effects from adding codes that are only temporarily covered by Medicare during the PHE.

Response: The addition of the proposed telehealth services and corresponding codes to the measures beginning with the 2021 performance period will ensure that the cost measures adapt to the changes in care provision and service utilization caused by the PHE. As we explained in the proposed rule (85 FR 50294), we do not consider the addition of the proposed codes for telehealth services to be a substantive change as they do not represent a new category of costs or change the intent of the measure and so we do not believe it is necessary to conduct specific testing on their inclusion for public feedback. Our intent is only to update the list of codes in the service categories already captured in the measures. For this reason, we do not anticipate that these services will have an impact on the measures' ability to accurately capture cost of care or clinician performance on measures in a way that is different from other similarly appropriate services that are currently included in the measures.

Furthermore, not all telehealth services billed by a clinician will be automatically included in all of the cost measures. Specific telehealth services will be included in a given measure if they are clinically relevant (for example, contain a relevant diagnosis code) to the trigger event of the measure (for example, a knee arthroplasty). For this reason, clinicians in areas with COVID–19 outbreaks would not be adversely affected by the addition of these services to the cost measures; only telehealth services they bill in relation to the care provided for the trigger event would be included in the cost measure. The service assignment logic and the specific telehealth codes that we

proposed to include for each cost measure are available in the measure codes list files on the CMS website (*http://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*).

Upon the expiration of the PHE, Medicare will no longer include on the Medicare telehealth list the services that were added on an interim basis during the PHE for COVID–19, which we expect will result in the reduction of telehealth utilization in place of the corresponding in-person services already included in the cost measures. As the cost measures include the costs of services found empirically in the Medicare claims data, only services actually billed by clinicians, whether furnished in-person or via telehealth, would be included in service assignment for the measure. For this reason, we do not anticipate any downstream effects of adding to the cost measures codes that may be temporarily billed as telehealth services. As we anticipate that telehealth will continue to occupy an important role in care delivery, we do not plan to remove the proposed telehealth codes from the cost measures unless they are no longer applicable or payable by Medicare. We will continue to monitor the telehealth services for potential updates, if necessary, as part of ongoing measure maintenance for the cost measures.

Comment: One commenter indicated that the rationale for including telehealth costs within the cost performance category measures was understood, but urged CMS to consider developing hardship exemptions from such telehealth cost attribution and/or providing bonus points for cost measures that include telehealth services to help adjust for the upfront investments that solo practitioners and small practices would need to put forth to upstand and scale telehealth platforms during the PHE for COVID–19.

Response: We appreciate the commenter's feedback. The proposed telehealth codes would be added to the cost measures to capture costs of services clinicians have continued to provide via telehealth and not in person during the PHE and that are related to the trigger event for a given measure. There is no separate telehealth cost attribution for which these codes would be used. Performance under the cost measures will be assessed according to existing MIPS scoring policies and any new policies we are finalizing in this rule. With regard to hardship exemptions, we provide the option for clinicians to submit applications requesting reweighting for one or more MIPS performance categories based on extreme and uncontrollable circumstance.

After consideration of the public comments, we are finalizing our proposal to add costs associated with certain telehealth services and their corresponding codes to the previously established cost measures as proposed, beginning with the 2021 performance period.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 through 59777), and the CY 2020 PFS final rule (84 FR 62980 through 62990). We also refer readers to § 414.1305 for the definition of improvement activities and attestation, § 414.1320 for the performance period, § 414.1325 for the data submission requirements, § 414.1355 for the improvement activity performance category generally, § 414.1360 for data submission criteria, and § 414.1380(b)(3) for improvement activities performance category scoring.

In the CY 2021 PFS proposed rule (85 FR 50294), beginning with the CY 2021 performance period and future years, we proposed: (1) Changes to the Annual Call for Activities: An exception to the nomination period timeframe during a PHE; and a new criterion for nominating new improvement activities; (2) a process for HHS-nominated improvement activities; and (3) to modify two existing improvement activities. In addition, in the March 31st COVID–19 IFC (85 FR 19276 through 19277), we adopted, on an interim final basis, a policy to add one new improvement activity to the Inventory for the CY 2020 performance period in response to the PHE titled ''COVID–19 Clinical Trials.'' The activity required that a clinician must attest to participation in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection and report their findings through a clinical data repository or clinical data registry. Following the publication of March 31st COVID–19 IFC, we received several inquiries from stakeholders requesting further information on whether a clinician working with COVID–19 patients who provides their data to a clinical data registry, without participating in a clinical trial, may get credit for this activity. In our efforts to provide clarification we realized that we needed to codify changes in the regulation for this improvement activity to apply in the manner that was intended. Therefore, in the September 2nd COVID–19 IFC (85 FR 54848 through 52851), we issued an IFC in which we adopted a modification, on an interim final basis, to the COVID–19 improvement activity that for CY 2020 continuing into CY 2021, the improvement activity IA_ERP_3 titled ''COVID–19 Clinical Data Reporting with or without Clinical Trial'' would include: (1) Clinicians participating in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection who report their findings through a clinical data registry for the duration of their study; or (2) clinicians participating in the care of a patient diagnosed with COVID–19 who simultaneously submit their clinical patient data to a clinical data registry for research.

(b) Improvement Activities Inventory

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination

form available at *www.qpp.cms.gov* during the Annual Call for Activities.

(A) Timeframe for the Annual Call for Activities

(aa) Currently Adopted Timeframe

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form available at *www.qpp.cms.gov* during the Annual Call for Activities.

In the CY 2019 PFS final rule (83 FR 59781 through 59782), we finalized to change the performance year for which nominations of prospective new and modified improvement activities would apply, such that beginning with the CY 2019 performance period and for future years, improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in a future year. In addition, we finalized to change the submission timeframe for the Annual Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations beginning with the CY 2019 performance period.

(bb) Exception During Public Health Emergencies

The unprecedented PHE [125] for COVID–19 has brought to our attention the necessity of having the flexibility to consider nominations of new improvement activities to the Inventory outside the established Annual Call for Activities nomination period. We believe having the flexibility to consider nominations during a PHE is important because of the nature of a PHE; we want the ability to consider relevant improvement activities while the emergency is ongoing. We refer readers to the CY 2019 PFS final rule (83 FR 59779) for a complete definition of PHE and its application to inclusion criteria for new improvement activities.

As a result, beginning with the CY 2021 performance period, we proposed to make an exception to the established timeframe, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). We noted that we continue to believe it is important for stakeholders to be able to comment on improvement activities. Therefore, any improvement activity considered for inclusion in the Inventory would be finalized through a future rulemaking. We invited public comments on the proposal.

We received public comments on the proposal to make an exception to the established Annual Call for Activities timeframe, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported adding flexibility to consider nominations of new improvement activities outside the established Annual Call for Activities nomination period during a PHE, noting that it will allow new improvement activities to reflect real-world events, spur innovation, and allow for timely responses to a PHE.

Response: We appreciate the support for establishing the flexibility to consider nominations of new improvement activities outside the established Annual Call for Activities nomination period during a PHE. We believe that this flexibility will allow us to be responsive to the needs of clinicians during PHEs.

Comment: A few commenters supported adding this flexibility, but recommended that data validation and other guidance for how to receive credit be provided when activities were introduced, that new additions allow for a 90-day performance period with a ''ramp-up'' period, and that feedback be provided on why certain submitted improvement activities were not accepted.

Response: We appreciate the additional comments related to data validation, a ''ramp-up'' period, and feedback for submitted activities that are not accepted. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). We noted that we continue to believe it is important for stakeholders to be able to comment on improvement activities. Therefore, any improvement activity considered for inclusion in the Inventory would be finalized through a future rulemaking. For improvement activities related to a PHE, we plan to issue subregulatory guidance as soon as feasible following adoption of the new improvement activity. Improvement activities added during a PHE will be subject to the same 90-day performance period requirement as all improvement activities and will be available for reporting as stated in the regulation that the new activity is finalized. There will not be an added ''ramp-up'' or trial period as the goal of this added flexibility is to encourage clinicians to begin addressing the PHE as soon as possible and get credit for early efforts.

Comment: We received a few comments stating that the improvement activity submission and acceptance process through the Annual Call for Activities is unclear. Commenters stated that they are uncertain what types of improvement activities we are looking for, and the reasons improvement activities are not accepted are not explicitly provided. A few commenters recommended that we should better incorporate the suggestions of physicians and specialty societies and allow more time for providers to adjust

[125] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

to changes to improvement activities before they take effect.

Response: We understand the need for feedback on why certain submitted improvement activities were not accepted during the Call for Activities and will do our best to provide clear responses when not accepting suggested activities in the future. In the CY 2018 Quality Payment Program final rule (85 FR 53656 through 53660), we provide details regarding adding new activities through the Annual Call for Activities, the criteria for nominating new improvement activities, and the submission timeline for nominating new improvement activities. In addition, each year we provide subregulatory guidance that contains comprehensive information regarding the Annual Call for Activities. We refer readers to these documents on the Quality Payment Program website in the resource library at *https://qpp.cms.gov/about/resource-library*. After consideration of the public comments, we are finalizing this policy as proposed.

(B) Criteria for Nominating New Improvement Activities

In the CY 2019 PFS final rule (83 FR 59778 through 59779), we adopted one new criterion and removed a criterion from the improvement activities nomination criteria. We also clarified our considerations in selecting improvement activities.

(aa) Currently Adopted Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule, we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria; stakeholders should apply one or more of the below criteria when submitting nominations for improvement activities (82 FR 53660). In addition, in the CY 2019 PFS final rule (83 FR 59779) we finalized to add a ''public health emergency as determined by the Secretary'' to the criterion below.

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary; or
- CMS is able to validate the activity.

(bb) New Criteria

In addition to the aforementioned considerations, when considering improvement activities for possible inclusion in MIPS, we proposed that beginning with the 2021 Call for Activities, MIPS improvement activities submitted should be linked to existing and related quality and cost measures, as applicable and feasible. Stakeholders that select this criteria would be required to provide a rationale describing how they believe their improvement activity correlates to other performance category measures as a part of the Call for Activities. We noted that we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities.

Therefore, we proposed to adopt an additional criterion entitled ''Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible'' to the criteria for nominating new improvement activities beginning with the CY 2021 performance period and future years. We noted that if the proposal to add one criterion is adopted as proposed, stakeholders should apply one or more of the below criteria when submitting nominations for improvement activities beginning with the CY 2021 performance period and future years:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary;
- Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible; or
- CMS is able to validate the activity.

We received public comments on the proposal to adopt an additional criterion entitled ''Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible'' to the criteria for nominating new improvement activities. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal for improvement activities to be linked to existing and related MIPS quality and cost measures, noting that it could offer more visibility for cost measures, synchronize cost and quality measures, and help reduce reporting burden.

Response: We appreciate commenters' support for this policy. We believe these policies will also facilitate cohesive MVPs in the future.

Comment: A few commenters supported linking improvement activities to MIPS quality and cost measures but recommended deferring the requirement until the MIPS MVPs have been implemented and assessed. Commenters also recommended linking new improvement activities to existing MIPS QCDR measures, adding more improvement activities that are focused on specific specialties and clinician types and can be more easily linked to quality and cost measures, and allowing new improvement activities to be added even when they cannot be linked to existing quality and cost measures.

Response: We appreciate the support for linking improvement activities to MIPS quality and cost measures. To clarify, linking nominated improvement activities to existing and related MIPS quality and cost measures is not a stand-alone requirement. In the proposed rule, we proposed that beginning with the 2021 Call for Activities, MIPS improvement activities submitted should be linked to existing and related MIPS quality and cost measures, as

applicable and feasible. Stakeholders should apply one or more of the listed criteria when submitting nominations for improvement activities. The quality and cost performance categories are two of the four performance categories required by statute in MIPS. We believe that the improvement activities should be linked to existing and related quality and cost measures rooted in statute. We applied a similar criterion for the quality measures as finalized in the CY 2020 PFS final rule (84 FR 62954) such that beginning with the 2020 Call for Measures process, MIPS quality measure stewards will be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards will be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities as a part of the Call for Measures process. In addition, we have finalized in the CY 2020 PFS final rule (84 FR 63063 through 63065) that QCDRs will be required to link their QCDR measures to existing and related cost measures and improvement activities, as applicable and feasible.

Comment: Several commenters supported making changes to how MIPS improvement activities are developed and added to the Improvement Activity Inventory, including selecting improvement activities that promote modern connected technologies, incent clinicians who participate in COVID–19 efforts, encourage clinicians who serve as preceptors for students, promote integration of registered dietitians on population management care teams, incent bone health, and expand the list of health equity-related improvement activities.

Response: We encourage stakeholders to submit nominations for activities through the Call for Activities period where nominations may include promoting modern connected technologies, incenting clinicians who participate in COVID–19 efforts, encouraging clinicians who serve as preceptors for students, promoting integration of registered dietitians on care teams, incenting bone health, and increasing the number of health equity-related improvement activities. Regarding the latter, we currently have an improvement activity in the Inventory, IA_AHE_6, titled ''Provide Education Opportunities for New Clinicians'' that is weighted high for participation as a preceptor for clinicians in-training that encourage clinical rotation in community practices in small underserved, or rural areas. If the commenter believes an additional improvement activity for preceptors should be included in the Inventory, we encourage them to submit a nomination through the Call for Activities. In addition, in the September 2nd COVID–19 IFC (85 FR 54848 through 52851), we adopted, on an interim final basis, a policy to add an additional improvement activity to the Inventory for CY 2020 and CY 2021. We also refer readers to Appendix 2 of the CY 2021 PFS proposed rule (85 FR 50664 through 50665) for further details and Appendix 2 of this final rule for responses to comments received and finalization of the COVID–19 improvement activity, IA_ERP_3, titled ''COVID–19 Clinical Data Reporting with or without Clinical Trial.'' Furthermore, in section IV.A.3.c.(3)(b)(i) of this final rule, we are finalizing an exception to the established Annual Call for Activities timeframe, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. In section IV.A.3.c.(3)(b)(ii) of this final rule, we are also finalizing a process for HHS-nominated improvement activities. Combined, we believe these two new policies will help streamline efforts to create MIPS policies in a timely manner in response to PHEs.

After consideration of the public comments, we are finalizing this policy as proposed.

(ii) HHS-Nominated Improvement Activities

(A) Background

As stated in the CY 2021 PFS proposed rule (85 FR 50295), this unprecedented PHE for COVID–19 has brought to our attention the necessity of having the flexibility to consider nominations of new improvement activities to the Inventory outside the Annual Call for Activities nomination period and process.'' We noted that we believe that we should have the flexibility to nominate activities from within HHS. We noted that the federal government is uniquely positioned to quickly address administration goals versus the public sector in pertinent areas that may have national impact to improve the health care system. For example, CMS has established the CMS Strategic Initiatives which provides 16 distinct focus areas including Patients over Paperwork. The CMS Strategic Initiatives focus areas aim to empower patients and unleash innovation while transforming the health care system. We also noted that we believe that goals such as the CMS Strategic Initiatives deliver better value and results for patients through competition and innovation. To accomplish goals included in agency-wide plans, such as the CMS Strategic Initiatives, there are instances when it is necessary to accept HHS-nominated improvement activities outside of the Call to advance these type of goals in an expedited manner. We referred readers to *https://www.cms.gov/About-CMS/Story-Page/our-16-strategic-initiatives* for more information about CMS strategic initiatives and to *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork* for more information about Patients over Paperwork.

(B) HHS-Nominated Improvement Activities Process

Beginning with the CY 2021 performance period and future years, we proposed that we would consider HHS-nominated improvement activities all year long in order to address HHS initiatives in an expedited manner. These HHS-nominated improvement activities would be subject to the same criteria for nominating new improvement activities as discussed in the CY 2021 PFS proposed rule (85 FR 50295 through 50296) titled ''Criteria for Nominating New Improvement Activities.'' In addition, the HHS-nominated activity would need to apply the criteria of: ''aligned with at least one of the HHS goals, when feasible and appropriate'' to the nominated activity. Further, the HHS-nominated improvement activity would be assessed for the most appropriate subcategory; we refer readers to § 414.1355(c).

We noted that we continue to believe it is important for stakeholders to be able to comment on these HHS-nominated improvement activities. Thus, we would propose any HHS-nominated improvement activities through rulemaking. In such proposal, we would specifically request comment on whether stakeholders agree the activities improve clinical practice or care delivery.

We received public comments on the proposal that we would consider HHS-nominated improvement activities all year long to address HHS initiatives in an expedited manner. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to allow for HHS-nominated improvement activities all year long.

Response: We appreciated the support for allowing HHS-nominated improvement activities all year long. This will allow us to be responsive to HHS initiatives.

After consideration of the public comments, we are finalizing this policy as proposed.

(iii) Changes to the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), and Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538) for our previously finalized improvement activities Inventory. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2020* for a complete list of the most current list of improvement activities. In the CY 2021 PFS proposed rule, we did not propose to remove any previously adopted improvement activities. We also proposed to modify two existing improvement activities for the CY 2021 performance period and future years. In this final rule, we are finalizing the modification of two existing improvement activities, removal of one obsolete improvement activity, and adoption of the COVID–19 improvement activity added via IFC. We refer readers to the below and Appendix 2 of this final rule for more details.

(A) Removal of IA_CC_5

Subsequent to publication of the proposed rule, we became aware that one underlying program, which forms the basis for one improvement activity, has expired. The improvement activity is: IA_CC_5, titled ''Partner in Patients Hospital Engagement Network.'' The Partner in Patients Hospital Engagement Network activity description requires membership and participation in a CMS Partnership for Patients Hospital Engagement Network which ended March 31, 2020, and may be found at *https://innovation.cms.gov/innovation-models/partnership-for-patients*. Because the Partnership for Patients Hospital Engagement Network has ended and performance of this activity will no longer be possible starting with the CY 2021 performance year, this improvement activity is obsolete; therefore, we are finalizing removal of this improvement activity beginning with the CY 2021 performance year/2023 MIPS payment year to avoid any potential confusion. We refer readers to Appendix 2 of this final rule for more details.

(B) Finalization of COVID–19 Improvement Activity Added via IFC

The COVID–19 pandemic was deemed a PHEby the Secretary of the Department of HHS. In response, in the March 31st COVID–19 IFC (85 FR 19276 through 19277), we added one new improvement activity to the Improvement Activities Inventory for the CY 2020 performance period in response to the PHE titled ''COVID–19 Clinical Trials.'' As described in the March 31st COVID–19 IFC, this improvement activity promotes clinician participation in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection. We stated that to receive credit for this improvement activity, a clinician must attest to participation in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection and report their findings through a clinical data repository or clinical data registry (85 FR 19276). In that IFC, we also stated that we believe that participation in this activity would likely result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID–19 and drive care improvements (85 FR 19277). We stated that we believe that encouraging clinicians to utilize an open source clinical data repository or clinical data registry for data reporting will bring the results of their research to the forefront of healthcare far quicker than if it goes through the cycle of peer review and publishing (85 FR 19277). In addition, we stated that we believe that centralized data could improve clinical practice and care delivery (85 FR 19277). As stated in the September 2nd COVID–19 IFC (85 FR 54848 through 52851), following the publication of the March 31st COVID–19 IFC, we received several inquiries through meetings, email correspondence, and Quality Payment Program help desk requesting further information on whether a clinician working with COVID–19 patients who provides their data to a clinical data registry, without participating in a clinical trial, may get credit for this activity. The Quality Payment Program help desk tracks, documents, and resolves inquiries submitted by MIPS eligible clinicians and groups. Stakeholders may submit inquiries to the help desk via 1–866–288–8292 (Monday–Friday 8 a.m.–8 p.m. ET) or email *QPP@cms.hhs.gov*. Some stakeholders believed that clinicians providing care to patients with COVID–19 outside of a clinical trial that report those data through a clinical data registry should receive credit for this activity. It came to our attention that clinical data registries not only collect data as part of clinical trials, but also collect data from clinicians not participating in clinical trials. The improvement activity as written was causing confusion for clinicians and groups attempting to meet the needs of patients and address gaps in research. Since IA_ERP_3 titled ''COVID–19 Clinical Trials'' was established, this improvement activity has been the subject of approximately 30 percent of the inquiries to the Quality Payment Program help desk, demonstrating the desire for clinicians to improve clinical care and overall outcomes for patients diagnosed with COVID–19 by conducting this improvement activity, but also indicating the need for further clarity in its activity description.

As a result, we expanded the improvement activity to include clinicians participating in the care of a patient diagnosed with COVID–19 who simultaneously submit their clinical patient data to a clinical data registry for research. Thus, in order to receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) Participate in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID–19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID–19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. We also modified the improvement activity title to reflect this change.

For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) The receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes.

Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical

requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.

As stated in the March 31st COVID–19 IFC, we continue to believe that participation in this activity is likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients. We believe that all clinical data gathered in the treatment of patients diagnosed with COVID–19 may be helpful in finding a solution to end this pandemic. We believe encouraging clinicians collectively to utilize a clinical data registry for data reporting could facilitate sharing of data for use in additional clinical studies with larger sample sizes. These additional and larger clinical studies are likely to identify efficacy of certain treatments, which in turn could result in wider improvements in health outcomes, including reduced severity and mortality due to COVID–19 across the nation. This could benefit patients nationwide as well as improve clinical practice and care delivery for the patients of the clinician attesting to this improvement activity. We would like to encourage all clinicians to provide data through an open source clinical data repository or clinical data registry, meaning that the results of research are made public, including via publications and scientific data sources, which enables reuse, increases transparency, and facilitates reproducibility of research results. Furthermore, a clinical data registry may allow such data to be publicly available which may be used for research.

As stated above, we previously added the improvement activity to the Inventory for the CY 2020 performance period only in response to the PHE for COVID–19. In the IFC, we extended the newly modified COVID–19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the increased rate of COVID–19 infection we were experiencing nationwide. We anticipated the need for COVID–19 clinical trials and data collection/sharing through registries to continue through CY 2021 at which time we would reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We wanted eligible clinicians to be able to attest to this improvement activity if it is still pertinent. We believed that participation in this improvement activity was likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID–19.

In this final rule, we are providing summary of public comments and our responses as well as finalizing the addition of this COVID–19 improvement activity and its subsequent modification and continuation. We refer readers to Appendix 2 of this final rule for more details.

(4) Promoting Interoperability

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record technology (CEHRT) as a performance category under the MIPS. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category.

(b) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2020 PFS final rule at § 414.1320(f)(1) (84 FR 62992), for purposes of the 2023 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2023 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within CY 2021, up to and including the full CY 2021 (January 1, 2021 through December 31, 2021).

For the 2024 MIPS payment year and each subsequent MIPS payment year, we proposed to add § 414.1320(g)(1), which would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. As discussed in the CY 2021 PFS proposed rule (85 FR 50297), the proposal aligns with what we proposed (and subsequently finalized) for the EHR reporting period in CY 2022 for the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) (85 FR 58966 through 58967). We stated that we believe this would be an appropriate performance period because it would offer stability and consistency for eligible clinicians reporting for the Promoting Interoperability performance category.

We requested comments on the proposal and the following is a summary of the comments we received and our responses.

Comment: Many commenters appreciated the continuation of the flexibility of being able to choose a 90-day performance period, which allows more eligible clinicians to successfully participate in the Promoting Interoperability performance category. A few commenters believe that 90 days is a sufficient amount of time to capture the necessary information required for the Promoting Interoperability performance category and allows the opportunity to update or implement new and innovative technology through the course of the CY without fear of negatively impacting performance data. Several commenters supported our proposal because it aligns with the EHR reporting period for eligible hospitals and CAHs adopted for the Medicare Promoting Interoperability Program.

Response: We agree that keeping the performance period to a minimum of 90 consecutive days affords MIPS eligible clinicians the flexibility they may need to develop and update their evolving EHRs. We believe aligning the length of the Promoting Interoperability Performance category performance period with the EHR reporting period for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs will reduce health IT burden across EHR systems in the clinician and hospital settings.

Comment: Several commenters suggested that we make the Promoting Interoperability Performance category performance period any continuous 90-day period for the remainder of the Quality Payment Program. One stated that by providing continued program stability, CMS allows clinicians and groups to focus more on caring for patients and improving interoperability and less on prescriptive reporting requirements.

Response: We agree and proposed that the performance period for the 2024 MIPS payment year and each subsequent MIPS payment year would be a minimum of a continuous 90-day period within the calendar year.

After consideration of the comments we received, we are finalizing the proposal for the 2024 MIPS payment year and each subsequent MIPS payment year to establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. We codified this policy at § 414.1320(g)(1).

(c) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure Under the Electronic Prescribing Objective

As discussed in the CY 2021 PFS proposed rule (85 FR 50297 through 50298), stakeholders have continued to express concern that it is still too premature to require the Query of PDMP measure because PDMPs are still maturing in their development, use and integration with EHRs. We proposed to make the Query of PDMP measure under the Electronic Prescribing objective optional and eligible for 10 bonus points in CY 2021. This would represent an increase in the amount of the bonus points for the Query of PDMP measure from 5 points to 10 points to reflect the importance of this measure and to further incentivize clinicians to perform queries of PDMPs.

We solicited comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that CMS should maintain the Query of the Prescription Drug Monitoring Program (PDMP) measure as optional. One commenter stated that many clinicians will not be able to fulfill this measure because not all clinicians prescribe controlled substances.

Response: We appreciate commenters for their support for maintaining the Query of PDMP measure as optional for the performance period in CY 2021 and allowing time for further progress around EHR–PDMP integration efforts minimizing the burden on MIPS eligible clinicians. We believe this will provide an opportunity for capable implementers to report on and earn bonus points for fulfilling the optional measure. Additionally, eligible clinicians who choose not to report on the Query of PDMP measure or are unable to report on this optional measure may still earn a full score for the Promoting Interoperability performance category.

Comment: Commenters indicated that clinicians have made great strides in their adoption of PDMPs despite a continuing lack of interoperability across many systems; therefore, they supported the measure remaining optional. Some commenters stated that it should not be required because it is challenging to electronically report due to the additional documentation and verification requirements with an external system, which creates unnecessary burden for clinicians. Another commenter expressed concern that until the information found within PDMPs is easily and seamlessly integrated into health IT systems that this type of EHR functional-use measure will be burdensome and require multiple actions outside of the clinical workflow. One commenter noted concerns that separate sign-in to a non-integrated PDMP requires hand entry of demographic data elements to search for a specific patient, which may increase the probability of erroneously matching a patient to another individual's health information, which in turn raises patient safety concerns. For those reasons, the commenters support CMS' proposal to maintain the Query of PDMP measure as optional for the performance period in CY 2021.

Response: We agree with the commenters' concerns and the importance of working towards improved EHR–PDMP integration. Keeping the Query of PDMP measure as optional for CY 2021 would allow states and other stakeholders an additional year to make further progress on developing functionality to support better integration of PDMPs within clinical workflows.

Comment: One commenter stated that the use of PDMPs is a proven means to increase accountability in opioid prescribing practices by providing information directly to the clinician that facilitates the coordination of multiple medications. Also, it has been proven to help prevent adverse drug interactions. The commenter concurred that PDMPs increase patient safety by assisting prescribers in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Expanding the use of PDMPs is a component of a broader strategy to prevent opioid abuse and ensure the safe, legal, and responsible prescribing of opioids for those who need them. The commenter also agreed that improving prescribing practices by use of PDMPs should reduce hospitalizations, emergency room visits, and the social challenges associated with the opioid epidemic. They believe that this not only demonstrates the importance of the measure, but also signals it will likely become a required Promoting Interoperability performance category measure in the future.

Response: We agree that PDMPs are an important tool to support clinicians' efforts to coordinate multiple medications, and increase patient safety by ensuring safe, legal and responsible prescribing. With the many benefits of clinicians querying PDMPs, we are finalizing the policy as proposed for the 2021 performance period. We plan on reevaluating this measure in future years to determine whether integration efforts have enabled improvements in PDMP querying.

Comment: A commenter stated that while they understand that CMS wants to limit burden regarding the implementation and integration of PDMP queries, the commenter is concerned about the potentially negative effect on patient outcomes occurring due to insufficient querying of PDMPs amid the current opioid epidemic. Thus, the commenter suggested CMS move this measure from optional to required as soon as possible.

Response: We understand the importance of implementation and integration of PDMP queries and effects on patient outcomes for the opioid crisis and during the PHE. We also recognize that various state programs are still maturing toward the development of robust EHR–PDMP integration. We will continue to collaborate with our partners in ONC on how to advance standards surrounding PDMP functionality and integration. Keeping the Query of PDMP measure as optional for the performance period in 2021 would allow states and other stakeholders an additional year to make further progress on developing functionality to support better integration of PDMP use within clinical

workflows, which is necessary before we will propose to require this measure.

Comment: Many commenters appreciated and supported increasing the bonus from 5 to 10 points for this measure to reflect the importance of this measure and to further incentivize clinicians to perform queries of PDMPs. A commenter agreed with the proposed increase because it emphasizes the importance of the measure as it relates to improved patient safety and incentivizes clinicians to expand the use of PDMPs. Another commenter stated that the increase of the bonus points for the Query of PDMP measure from 5 to 10 points, not only demonstrates the importance of the measure, but also signals it will likely become a required Promoting Interoperability measure in the future.

Response: We appreciate the overwhelming support and agree that our proposed approach emphasizes the importance of the measure as it relates to improved patient safety and incentivizes clinicians to expand the use of PDMPs.

Comment: One commenter did not support increasing the value of this measure from 5 points to 10 points. Instead, they suggested that CMS keep the bonus at the current 5 points, because they believe most vendors who plan on implementing functionality for this measure have done it, and that groups are currently attesting for it.

Response: We disagree and believe that increasing the points from 5 to 10 points emphasizes the importance of conducting PDMP queries and the importance of this activity for patient outcomes during the PHE and for the opioid crisis. Solo and small practices may have more difficulties incorporating PDMP into practice than larger groups; therefore, we want to incentivize all clinicians to adopt this measure.

After consideration of the comments received, we are finalizing the proposal to maintain the Electronic Prescribing objective's Query of PDMP measure as optional for the performance period in CY 2021. We are also finalizing the proposal to increase the amount of the bonus points for the Query of PDMP measure from 5 points to 10 points for performance periods in CY 2021.

2. Health Information Exchange Objective

a. Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the CY 2019 PFS final rule (83 FR 59807 through 59812), we established a new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure by combining the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure. To better reflect specific actions required by the measure's numerator and denominator, we proposed to replace the word ''incorporating'' with the word ''reconciling'' in the name of the measure (85 FR 50299). The new name would read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.

We requested comments on the proposal and the following is a summary of the comments we received and our responses.

Comment: Several commenters agreed that the use of the word ''incorporating'' was confusing to clinicians and supported our proposal. Some stated that the new name better reflects the workflow associated with the measure.

Response: We appreciate the commenters support and agree that modifying the name to Support Electronic Referral Loops by Receiving and Reconciling Health Information measure reduces confusion for clinicians and is a more accurate representation of the measures.

Comment: Several commenters opposed the nomenclature change because it is confusing for clinicians when measure names are changed.

Response: We received significant stakeholder feedback that the proposed name change would more clearly reflect the existing policy. The measure is not requiring clinicians to input redundant information, but rather to review and reconcile what is received with what is already in the patient record.

Comment: A commenter supported the change to the name, but noted that ''reconciling'' may be impossible with certain patient data, so ''attempting to reconcile'' would be preferable.

Response: While we understand the commenter concern, the measure only requires reconciling the available data. Thus, we believe the new name accurately reflects the measure.

Comment: A commenter suggested CMS to maintain this name in future years, as this is the third change in 5 years.

Response: We believe that we are adopting a name that is reflective of the intent of the measure, which should result in no need to revise it in the near future.

After consideration of the comments received, we are finalizing the proposed change to the name of the measure as proposed. The new name is: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.

b. Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

As discussed in the CY 2021 PFS proposed rule (85 FR 50299 through 50302), we proposed an alternative measure for bi-directional exchange through an HIE under the Health Information Exchange objective.

We proposed to add the following new measure under the HIE objective beginning with the performance period in 2021: Health Information Exchange (HIE) Bi-Directional Exchange measure. We proposed to add this new HIE Bi-Directional Exchange measure to the HIE objective as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. We proposed that clinicians either may report the two existing measures and associated exclusions OR may choose to report the new measure. We proposed that the HIE Bi-Directional Exchange measure would be worth 40 points. We also proposed the HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response. We proposed that clinicians would attest to the following:

++ I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period.

++ The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners.

++ I use the functions of CEHRT for this measure, which may include technology certified to criteria at 45 CFR 170.315(b)(1), (b)(2), (g)(8), or (g)(10).

We requested comments on our proposals and the following is a summary of the comments we received and our responses.

Comment: The overwhelming majority of commenters supported the addition of the HIE Bi-Directional Exchange measure. Several stated that incentivizing participation in HIEs that support bi-directional exchange would contribute to a longitudinal care record for the patient and facilitate enhanced care coordination across settings. Several commenters supported the increased use and integration of HIEs

into the clinical workflow and applauded CMS for taking steps to incentivize bi-directional exchange with these systems. One commenter supported the measure because it removes the barrier of not having access to another clinician's ''Direct address'' to send transition of care information manually. The commenter stated that this is not only a step in the right direction both to promote increased HIE adoption and use, but also to move away from the existing Send/Receive Transitions of Care measures, which can be convoluted and onerous to optimize within EHR documentation and reporting workflows.

Response: We appreciate all the support for this new measure as we agree that there are many benefits to HIE participation.

Comment: Some commenters appreciated that the attestation statements require information exchange for all patients and all patient records without exclusion, or allowances for partial credit to ensure all patients will benefit from bi-directional exchange.

Response: We appreciate commenters' support and agree that an important feature of this measure is that it emphasizes enabling bi-directional exchange for all of an eligible clinician's patients.

Comment: A commenter worries the proposed new HIE Bi-Directional Exchange measure is unworkable in real-world practice settings and is likely to be cumbersome. The commenter stated that the proposed attestations assume clinicians know what HIEs their hospital uses, and its particular usage. The commenter noted that this generally is not the case and puts the clinician in a position of having to defer to others with this knowledge—an unnecessary and onerous task that increases burden.

Response: We understand that not all eligible clinicians are currently aware of the HIE arrangements utilized by the hospitals and other institutions in which they practice. However, we believe that in many cases eligible clinicians' institutions may be submitting data for MIPS on behalf of clinicians and will be able to assist clinicians with further information about the HIEs in which they participate. Furthermore, we encourage the HIEs whose services qualify to support clinicians in meeting this measure to reach out to participants in order to make them aware of how they can satisfy the measure.

Comment: Another commenter stated that the inclusion of this measure is premature because there are numerous ways that HIEs connect to EHRs. The commenter recommended that CMS partner with ONC to develop certification criteria as there is great variability among HIE connection requirements currently.

Response: We recognize that there is significant variation in the technology arrangements used by HIEs currently. Accordingly, in the third proposed attestation statement, we sought to allow for use of different CEHRT functions, which may support robust HIE connections. Moreover, we believe that HIEs are likely to continue to leverage different technology capabilities to connect to EHRs in accordance with local variations in technology implementation. While we believe it is important to move forward now with incentivizing eligible clinicians to establish robust connections with HIEs, we will continue to work with ONC to explore how the ONC Health IT certification program can further support integration between HIEs and EHRs.

As we stated in the proposed rule, we believe there are numerous certified health IT capabilities which can support bi-directional exchange with a qualifying HIE. For instance, participants may interact with an HIE by using technology certified to the criterion at § 170.315(b)(1) to transmit patient summary care records in the form of a C–CDA to the HIE, or using the technology certified to the criterion at § 170.315(b)(2) to receive and reconcile information received from the HIE into an EHR. Participants could also utilize API technology certified to either the criterion at §§ 170.315(g)(8) or (10) as finalized in the 21st Century Cures Act final rule (85 FR 25742), to enable an HIE to obtain data from a participant's EHR. We note that certified health IT modules meeting certification criteria beyond those mentioned in the proposed rule may also support exchange of information with an HIE for transitions of care, including: Certification criteria at § 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at § 170.315(e)(1) ''View, download, and transmit to 3rd party'' which supports patient access to their information; and the certification criterion at § 170.315(g)(6) ''Consolidated CDA creation performance'' which supports creation of a summary of care record.

However, we believe that we can provide more clarity in the third attestation statement regarding our intent to allow flexibility for clinicians to use different functions of CEHRT as appropriate to enable bi-directional exchange with an HIE that meets the requirements of the measure. While there are many certified technology capabilities which may support connections with HIEs, as described above, we wish to emphasize that clinicians are only required to use the certified functionality appropriate to their connection with an HIE necessary to support the measure actions. Accordingly, we are finalizing modifications to the third attestation statement, to read: ''I use the functions of CEHRT to support bi-directional exchange with an HIE.'' We believe that this revised statement will provide more clarity to stakeholders regarding the requirements of the measure.

Comment: Several commenters requested that this measure be added to the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. CMS should maintain program alignment by including the HIE Bi-Directional Exchange measure starting in the 2022 reporting year, only after the measure is finalized for inclusion in the program for eligible hospitals and CAHs.

Response: We appreciate the commenters' suggestion to include the HIE Bi-Directional Exchange measure in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. We may consider adding this measure in future rulemaking. We believe that the benefits that could be reaped by implementing the measure for the 2021 performance period for MIPS eligible clinicians do not warrant a delay of a year for alignment. We disagree that CMS should maintain program alignment with the Promoting Interoperability Program and delay implementing this measure by starting in the 2022 performance period. Due to the PHE and the importance of HIE's enabling enhanced use of telehealth and telemedicine for obtaining and aggregating patient information it is important to implement for the 2021 performance period.

Comment: A commenter stated that the measure fails to account for the significant expense to clinicians who wish to report this new measure. HIEs are expensive, often requiring monthly or yearly subscription fees. Many operational hurdles exist for bi-directional exchange for ''every patient encounter, transition or referral, and record stored or maintained in the EHR'' (section IV.A.3.c.(4)(c)(ii)). These hurdles include but are not limited to: The cost of HIE agreements and implementation, the ability of an HIE to implement interfaces capable of meeting

the standards of the measure, and the difficulty of logistics for healthcare organizations that exist across the jurisdictions of multiple HIE agencies. A commenter recommended that the measure requirements be relaxed for the first year in order to implement the processes through the EHRs and to educate clinicians on utilization and workflows. A suggestion would be to treat this like the measures of the Public Health and Clinical Data Exchange objective thus allowing ''credit'' for being in the process of implementation and/or testing to be compliant with the new measure.

Response: We recognize that there may be additional costs related to establishing a connection with an HIE. Accordingly, we proposed to make this measure optional, and understand that many eligible clinicians may wish to use the capabilities of their CEHRT which represent investments which eligible clinicians have already made. However, we understand that many eligible clinicians are also seeking to take advantage of robust HIE connections which can enable information exchange in an advanced fashion, and we are seeking to incentivize these investments as part of the Promoting Interoperability performance category.

As this measure is optional and attestation-based, we also do not believe it is necessary to provide a ''phase-in'' period for this measure, or to provide credit for eligible clinicians that are in the process of establishing these connections. These clinicians may continue to report on the existing numerator-denominator measures for the HIE objective and switch to reporting on the optional HIE Bi-Directional exchange measure at a future date when they are prepared to do so.

Comment: Several commenters stated that the attestation statements for this measure appropriately reflect the expectations for information exchange capabilities. The commenters believed that the attestation statements are sufficiently broad and allow for the different ways health care providers connect with HIEs.

Response: We appreciate the commenters support.

Comment: A commenter encourages CMS to expand the measure to include ''*HIEs, exchange frameworks, or other organizations focused on bi-directional health information exchange*'' since participation in a single HIE might not meet the measure's requirement to support HIE for ''every patient encounter, transition or referral.''

Response: We appreciate the commenters' concerns. The term ''HIE'' is intended to broadly refer to arrangements that facilitate the exchange of health information, and may include arrangements commonly denoted as exchange ''frameworks,'' ''networks,'' or using other terms. To qualify for the measure, an HIE or other exchange network may qualify to support clinicians in meeting the measure provided it qualifies under the attestation statements including providing the capabilities specified under attestation statement 1 to allow a clinician to enable bi-directional exchange for all of an eligible clinician's patient records and meeting the standard specified under attestation statement 2 related to facilitating non-exclusionary exchange.

Comment: A commenter suggested the first attestation statement be modified by replacing ''enable'' with ''attempt''. Another commenter stated that the second part of the first attestation is confusing: ''and record stored or maintained in the EHR during the performance period.'' EHRs interact with HIEs in different ways and clarification is requested.

Response: We appreciate the commenters' concerns. As we are offering a significant amount of points for this measure, we believe that ''enable'' more accurately reflects the high level of performance and the specific action we are expecting clinicians to take. Also, we understand that there is wide variation in HIE arrangements which may result in different modes of information exchange. The description of services in the first attestation statement would only require enabling of bi-directional functionality for the specified patient population and information. Eligible clinicians would not be required to adhere to specific guidance regarding what data is stored locally by the eligible clinicians EHR and what data is stored within the HIE, if any.

Comment: A commenter suggested that until there is more widespread connectivity and available information in the HIE space that CMS should remove the second attestation statement. Another commenter requested that to minimize burden, CMS remove the second attestation statement.

Response: We disagree that we should remove the second attestation statement, and believe that removing the attestation statement would not be consistent with the exchange behavior we are seeking to encourage through this measure, which is focused on the use of an HIE to exchange with any other clinician who may be involved in the care of any of an eligible clinician's patients. The second attestation statement is intended to ensure that an HIE which supports a clinician in attesting to this measure has the capacity to enable widespread exchange across a given health care market. We also believe that prioritizing those HIEs capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and which do not engage in exclusionary behavior when determining exchange partners, will encourage HIE networks to adopt wider connectivity.

Comment: A commenter stated that the requirement that ''bi-directional engagement occurs for all patients and all records'' is naïve. Newborn babies, for example, do not have information in an HIE, and it is a waste of resources for the system to send a query regarding them.

Response: The first attestation statement as proposed would require clinicians to attest that they have enabled bi-directional exchange for every patient record in their EHR. Enabling bi-directional exchange does not mean that an eligible clinician would be required to conduct information transactions that are not clinically necessary. Rather, it means that an eligible clinician has established the capabilities necessary to complete exchanges of information for their patients at the appropriate time.

Comment: One commenter was encouraged by CMS' proposal and supported CMS relying on yes/no measure attestations for this category as much as possible, which would minimize clinician reporting burden and aligns with how clinicians attest to the improvement activity performance category.

Response: We agree that this measure will provide an optional path for qualifying clinicians to earn credit under the HIE objective while reducing administrative burden associated with reporting on the current measures.

Comment: The definition of an HIE is broad and could apply to many existing entities across the country. A commenter requested that CMS provide some examples of HIEs that they consider to meet the definition of the measure. They added that it would be helpful if CMS could provide examples of the types of evidence that an organization might preserve and provide in case of an audit due to the broad nature of the attestation measure, and multiple sub-statements in which an organization must attest.

Response: We decline to provide a list of HIEs that meet the attributes specified

in the measure. We believe there are a wide number of organizations providing HIE services around the country which could effectively support clinicians who wish to attest to the measure, and we do not want to appear to endorse particular HIEs over others. We also recognize that the HIE space is rapidly changing, and additional organizations may emerge or evolve to meet the attributes described in the attestation statements following the publication of this final rule. In regards to audit documentation, eligible clinicians who choose to attest to this optional measure could support their attestation statements using a variety of materials, including: Agreements with the organization providing them with health information exchange services; materials from the organization that provides their HIE services describing their services in a manner consistent with the attestation statements; or systems documentation from their EHR vendor describing their connection to the HIE.

Comment: Several commenters suggested that CMS implement this new 'bi-directional engagement' replacement option immediately. However, the commenters stated that the threshold should not be every patient encounter. Instead, to make the measure reasonable, the threshold should be set at 50 percent of all eligible encounters. Another commenter suggested that CMS impose a lower threshold for performance. A commenter stated that, as this measure is new and robust connections with HIEs are still rare, they contend that this is an unreasonable requirement and recommend for the CY 2021 reporting year that it be modified to be ''a minimum of 10 percent of patient encounters and for a minimum of 10 percent of patient records transmitted during the performance period.'' Another commenter recommended that CMS consider partial credit for eligible clinicians and new sites being on-boarded to an HIE during the performance period.

Response: We appreciate the commenter's support. However, we disagree with the recommendation to set a threshold for the measure. The goal of this measure is to incentivize connections with HIEs that enable bi-directional functionality for all of the patient records in an eligible clinician's EHR. For clinicians with a robust connection available to an HIE, we do not believe that it would make sense to only enable this functionality for a subset of patients. Therefore, we decline to apply a threshold percentage to this measure. We understand that all eligible clinicians may not have a connection with an HIE that is capable of enabling bi-directional exchange for all of the patient records in an eligible clinician's EHR. However, in recognizing that this functionality is not available for all eligible clinicians, we have proposed that this measure would be optional. We also decline to provide partial credit for this measure as partial performance would not meet the goals of the measure. Our goal in proposing this measure is to incentivize the high standard of performance on health information exchange which can be achieved by establishing robust, bi-directional exchange capabilities facilitated by an HIE. We do not believe that allowing eligible clinicians to satisfy the measure based on a partial threshold would be consistent with incentivizing a high performance standard for the exchange of health information.

Comment: A commenter applauded CMS' desire to incentivize eligible clinicians to participate in HIEs while establishing a high performance standard for sharing information with other clinicians. Like many other practices, the commenter struggles with the ''Sending Health Information'' measure because many receiving health care providers and facilities have not implemented the technology necessary to receive and acknowledge the summary of care.

Response: We appreciate the commenter for their support.

Comment: Commenters suggested that CMS ensure that clinicians continue to have multiple options to meet the Health Information Exchange objective, as not all clinicians will have access to an HIE. The other issue facing practices is the cost of connecting with their local exchanges. High connectivity fees imposed by the HIE and/or the practice's EHR vendor can act as a significant deterrent to connectivity.

Response: We are only finalizing this measure as optional at this time, and recognize that many clinicians may prefer to continue to report using the existing HIE objective measures. We also agree and understand that there are costs associated with utilizing the capabilities of an HIE, and that all clinicians may not choose to assume these costs in addition to existing EHR investments.

Comment: A commenter recommended that CMS limit its HIE Bi-Directional measure conditions to that of exchange between unaffiliated health care provider entities regardless of whether they are using the same EHR product or participating in the same EHR-run HIE. Another commenter stated that more should be done to promote bi-directional exchange between unaffiliated entities and between disparate EHRs.

Response: While we believe that HIE arrangements which only permit exchange between the clinicians using the same EHR product may be useful for increasing interoperability among specific groups of clinicians, our goal with this measure is to incentivize exchange arrangements that allow for advanced interoperability across users of different vendor products. We agree that it is important to continue to encourage HIE arrangements that are capable of supporting exchange between different EHR systems. We note that there are a number of promising initiatives currently seeking to address this issue, and believe that incorporation of the HIE Bi-Directional Exchange measure will contribute to furthering these initiatives and making such services more widely available.

Comment: A commenter stated that while they support incentivizing interoperability of EHRs and the bi-directional flow of health information, the commenter did not believe it is appropriate or timely to introduce this new measure. Clinicians and EHR vendors, in particular, need additional time to comply with 21st Century Cures and subsequent rulemaking requirements regarding interoperability before this measure is added.

Response: We recognize that eligible clinicians participating in the Promoting Interoperability performance category are also impacted by the recently finalized provisions in the 21st Century Cures Act final rule. Our goal in finalizing this measure is to provide eligible clinicians with additional options to earn credit under the Promoting Interoperability performance category. We believe that the flexibility associated with this attestation-based measure can contribute to reducing administrative burden for eligible clinicians.

Comment: A commenter required clarification from CMS of whether an attestation response of ''yes'' could mean that the eligible clinician is prepared to implement the measure but their vendor is not yet capable of supporting the measure. Analogous to the public health measure with a similar attestation, the commenter suggested confirmation that an eligible clinician can attest ''yes'' to the proposed new measure when the clinician is ready and able to participate in the bi-directional exchange but for a limitation of the vendor.

Response: No. To earn the 40 points, the clinician must be connected to an HIE. If their vendor does not support

that connection, they do not fulfill the measure and would earn zero points.

Comment: A commenter stated that given that greater use of HIEs for bi-directional exchange will immediately contribute to enhanced care coordination across settings, this measure should not be optional for 2021, it should be required. Additionally, the commenter recommended that CMS continue to include this as a required measure in the MVPs.

Response: We appreciate commenters' support for this measure. However, at this time we do not believe it is appropriate to require clinicians to report this measure. For instance, we understand that some clinicians may not yet have access to an HIE that is capable of the functions reflected in the attestation statements. As the Promoting Interoperability performance category measures are considered foundational under the MVP framework, all Promoting Interoperability performance category measures would be available to those clinicians choosing to participate in MVPs.

Comment: A commenter requested CMS clarify the HIE being measured through the Promoting Interoperability performance category relates to *any* exchange of health information between HIE entities, meaning the measure does not restrict the exchange to only information sent and received from state HIEs or local health authority HIEs. Another commenter inquired as to whether national HIE networks would qualify.

Response: Nothing in the proposed requirements for this measure would limit qualifying HIE services to those entities managed by states or local health authorities. Moreover, we note that networks providing HIE services which are national in scope could also support eligible clinicians' successful attestation, provided they satisfy the finalized attestation statements.

Comment: A commenter questioned if there are requirements that dictate which HIE clinicians are expected to connect to. The commenter also noted that CMS should clarify whether clinicians are expected to connect to more than one (one in each state) HIE if they practice near a state border. The commenter also requested clarification surrounding a clinician's ability to fulfill this measure if there are no HIEs available for them to connect to.

Response: We did not propose any requirements for HIEs beyond those specified in the attestation statements for eligible clinicians, specifically, that the HIE permits a clinician to enable bi-directional exchange for all of the patient records within their EHR, and that the HIE meets the attributes described around exchanging information across unaffiliated health care providers and disparate EHR systems. We recognize that an organization providing HIE services could meet the conditions in the attestation statements while not facilitating a connection to every clinician or maintaining information on every patient in a given health care market, for instance, in cases where a health care market crosses a state line and the HIEs in each state do not yet share records. However, an eligible clinician may successfully attest to the measure statements as long as they are connected to at least one HIE in a manner consistent with the statements. We also understand that there may be some eligible clinicians who do not have access to any organizations providing HIE services at this time. While clinicians who do not participate in an HIE would not be able to attest for this measure, they would continue to be able to attest to the existing HIE objective measures.

Comment: Other commenters expressed concerns with the attestation statements as proposed. One commenter interprets the statements as meaning that clinicians are attesting that they have the *functional capability* to conduct bi-directional exchange for all patients during the performance period, not that physicians *must conduct* bi-directional exchange for all patients during the performance period. Another commenter recommended that CMS revise the attestation language proposed to ensure that the attesting clinician is not being held accountable for some features of his/her HIE that she might not know about or have control over.

Response: The first attestation statement for this measure requires eligible clinicians to attest that they participate in an HIE to enable bi-directional exchange for transactions for all of their patients. Enabling this functionality to occur for all of the patient records in an eligible clinician's HIE does not mean that clinicians would be required to share or request information when it is not clinically appropriate.

Comment: A commenter appreciated CMS' reference to CEHRT in the third attestation statement and suggested that CMS clarify that the minimum set of data needed to meet this measure's requirement for bi-directional exchange align with the Common Clinical Data Set (CCDS) soon to be the US Core Data for Interoperability (USCDI). The CCDS/USCDI serves as the baseline set of data required for interoperability and is what EHRs are commonly exchanging with HIEs today.

Response: The third attestation statement requires clinicians to attest that they use the functions of CEHRT to engage in bi-directional exchange. Similar to the guidance for the existing measures under the HIE objective, we are not defining a data set as part of the measure, but note that functions of CEHRT include technology certified to criteria which ensure a health IT module is capable of exchanging data contained in the CCDS, and subsequently the USCDI. As finalized in the 21st Century Cures Act final rule, existing references to the CCDS in these criteria will be updated to refer to USCDI consistent with the certification criteria in 45 CFR part 170.

Comment: A commenter requested clarification from CMS regarding the points a clinician is eligible for under this alternative measure. The proposed rule states that a clinician cannot earn more than 40 points, yet under the redistribution policy for exclusions, if a clinician can exclude the eRx measure, the 10 points for that measure are redistributed to the HIE measure, which would make it worth 50 points. The commenter requested that CMS clarify if this is still true if eligible clinicians choose this measure.

Response: The 40 points reflects the number of points available for the new HIE measure. It does not reflect the redistribution of points for the E-prescribing measure. If an exclusion is claimed for the E-Prescribing measure, the 10 points associated with that measure would be redistributed to the HIE objective resulting in 50 points available for the two existing HIE measures or the new HIE Bi-Directional exchange measure.

Comment: A commenter stated that clinicians should not have to attest to the capabilities of their HIE. There are great variances within HIE capabilities, and clinicians have no way of knowing all of them when selecting an HIE. Several commenters requested that HHS publish a list of common, widely known entities that would meet the definition of an HIE for the purposes of this measure.

Response: As discussed above, we decline to name specific entities who represent the attributes described in the second attestation statement, as we do not want to endorse specific organizations. Specifically, the second attestation statement specifies that clinicians attesting to the measure must participate in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate

EHRs, and does not engage in exclusionary behavior when determining exchange partners.

However, we believe that qualifying HIEs that can support eligible clinicians in attesting to this measure will have an interest in clearly communicating this fact to participants and potential participants. We encourage those HIEs that meet the description in the second attestation statement to publicly announce their availability to support this measure, both on their public website and through other communications methods. While a public announcement of availability to support this measure would not be required for an eligible clinician to leverage an HIE in order to attest to the measure, we believe that such activities will help to address commenters' concerns regarding how to determine whether an HIE meets the attributes described in the second attestation statement.

Comment: One commenter suggested CMS to allow for exclusions based on an individual patient's privacy request and potential state laws that would restrict information from being sent through an HIE.

Response: The first attestation statement requires eligible clinicians to attest that they participate in an HIE to enable bi-directional exchange for all of the patient records in their EHR. This is not intended to conflict with or supersede any applicable law including state, federal or tribal law governing access, exchange or use of electronic health information, the information blocking rules finalized at 45 CFR part 171, or any other patient privacy rules adopted by a specific HIE implementation such as policies permitting patients to opt out of sharing their health information through the HIE. Since attesting to this statement would not requiring sharing of information that is prohibited under existing laws, regulations and other policies, we do not believe it is necessary to specify additional exclusions. However, for additional clarity, we are revising the first attestation statement to specify that the bi-directional exchange is conducted ''in accordance with applicable law and policy.''

Comment: A commenter suggested phasing in language for every patient encounter beginning with transitions or referrals for new patients only. This is more reflective of where clinicians currently are with HIE integration and will encourage more robust future participation. In developing this new requirement, CMS should clarify that none of the language in the attestation statements conflict with applicable state law and guidance.

Response: We decline to phase in the measure requirement to enable bi-directional exchange based on subsets of patients as suggested by the commenter. We do not believe that there would be an appropriate reason to limit bi-directional exchange capabilities via an HIE to a subset of patients, such as new patients. Moreover, our goal in establishing this optional measure is to incentivize eligible clinicians to engage in HIE arrangements which enable bi-directional exchange for all of an eligible clinician's patient records, providing robust support for coordinated patient care. None of the requirements for this measure are intended to conflict with applicable federal, state, or tribal law or guidance. While eligible clinicians attesting to the first attestation statement attest that they have enabled bi-directional exchange for all of their patient records, enabling this functionality would not require clinicians to share information when sharing that information is prohibited by law or policy. We have revised the first attestation statement accordingly.

Comment: A commenter requested clarification on the content of information included in bi-directional exchange. It is unclear if, for example, portal messages must be included in the information exchanged with the HIE. The commenter requested guidance on how this can be implemented for practices on a portal that does not connect to an HIE.

Response: To successfully attest to this measure, the eligible clinician must use the capabilities defined for CEHRT to engage in bi-directional exchange via the HIE, which includes exchanging clinical data represented by the CCDS or included in the USCDI. Portal messages that are outside the CEHRT would not be included.

After consideration of the comments we received, we are adopting our proposals with the following modifications. Attestation statement 1 is as follows: ''I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition, or referral, and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy.''

Attestation statement 3 is as follows: ''I use the functions of CEHRT to support bi-directional exchange with an HIE.''

(d) Scoring Methodology

(1) Changes to the Scoring Methodology for the 2021 Performance Period

Table 48 summarizes the Promoting Interoperability performance category objectives and measures for CY 2021, including the changes adopted as final in the preceding sections of this final rule.

TABLE 48: Scoring Methodology for the Performance Period in CY 2021

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)
Health Information Exchange OR	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
Health Information Exchange (alternative)	HIE Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting	10 Points

Notes: The Security Risk Analysis measure is required, but will not be scored.

Comment: A commenter supported the modified scoring methodology for the Promoting Interoperability performance category, which was initially finalized beginning with the 2019 performance year. The scoring methodology is less cumbersome and easier to understand, and is effective in highlighting important objectives of the category. We are pleased that the scoring methodology will continue in 2021.

Response: We appreciate the commenter for their support of the modified scoring methodology and agree that the approach is less cumbersome and easy to understand.

(e) Additional Considerations

(1) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

We established a policy at § 414.1380(c)(2)(i)(A)(*5*) for the performance periods in 2017 through 2020 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act.

As in past years, we intend to use data from prior performance periods to further evaluate the participation of NPs, PAs, CRNAs, and CNSs in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. We have analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category and have discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. Although we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For the 2017 performance period, approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. For the 2018 performance period, approximately 34 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for the Promoting Interoperability performance category. In addition, the majority of MIPS eligible clinicians reported data for the Promoting Interoperability performance category for the 2017 and 2018 performance periods using the transition measure set. This set is unavailable for the 2019 performance period, which could have contributed to the decrease of MIPS eligible clinicians reporting data for Promoting Interoperability performance category. For the 2019 performance period, approximately 30 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for the Promoting Interoperability performance category, a reduction of 4 percent from the previous year.

For these reasons, we proposed at 85 FR 50302 through 50303 to continue the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2021, and to revise § 414.1380(c)(2)(i)(A)(*5*) to reflect the proposal.

The following is a summary of the comments we received and our responses.

Comment: A commenter supports this proposal until CMS can obtain more robust data. We continue to encourage the agency to provide technical assistance to clinicians with the goal of increasing EHR adoption and familiarity with the Promoting Interoperability performance category reporting requirements for all clinicians.

Response: We appreciate the commenter for their support in continuing the existing reweighting policy for NPs, PAs, CRNAs, and CNSs for the performance period in 2021 until we can obtain more robust data and

plan on continuing our support of stakeholders to increase EHR adoption and familiarity with the Promoting Interoperability performance category reporting requirements for all clinicians.

Comment: Another commenter appreciated the continued flexibility provided as CMS works to further assess the use of CEHRT by PAs and NPs. The commenter stated PAs are fully ready and capable to participate under the Promoting Interoperability performance category, with possible exception of small PA-owned practices that are unable to afford CEHRT systems that are fully compliant with current requirements. PAs in most practice settings have been using EHR systems for a number of years, often being the health profession who leads a practice's EHR system implementation and should be held to the same standards as physicians.

Response: We are pleased to hear that many PAs have the ability to participate in the Promoting Interoperability performance category and we hope those that are ready will submit data. For those who cannot, we will reweight the Promoting Interoperability performance category.

After consideration of the comments we received, we are finalizing our policy as proposed: We are continuing the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2021, and revising § 414.1380(c)(2)(i)(A)(*5*) to reflect this policy.

(2) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2020 PFS final rule (84 FR 63003 through 63004), we adopted a policy at § 414.1380(c)(2)(i)(A)(*4*) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs to other types of MIPS eligible clinicians who are NPPs (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2020. We stated that because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category.

For the reasons discussed in the proposed rule (85 FR 50302–50303), we proposed to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the performance period in 2021, and to revise § 414.1380(c)(2)(i)(A)(*4*) to reflect the proposal. We invited comments on the proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter thanked CMS for continuing to reweight the Promoting Interoperability performance category for therapists as they have not received any financial incentives or support for implementing EHRs.

Response: We appreciate the commenter for their support.

Comment: One commenter supports the proposal to continue reweighting the Promoting Interoperability performance category to zero for certain NPPs and psychologists reporting under MIPS. The commenter stated that psychologists have never been eligible for the financial incentives offered to physicians to promote the use of CEHRT and because many do not utilize CEHRT in their private practices, most psychologists would not have enough Promoting Interoperability performance category measures to successfully report. The commenter supports the proposal to continue to reweight the Promoting Interoperability performance category to zero as it will protect psychologist and certain other NPPs from being unfairly penalized.

Response: We appreciate the commenter's support and are finalizing our proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals.

After consideration of the comments, we are finalizing our proposals for the 2021 performance period to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals, and are revising § 414.1380(c)(2)(i)(A)(*4*) to reflect our policy.

(5) APM Entity Groups and APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

The APM scoring standard, codified at § 414.1370, is the MIPS scoring methodology applicable for MIPS eligible clinicians participating in a MIPS APM for the applicable MIPS performance period. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), the APM scoring standard was designed to reduce reporting burden for participants in MIPS APMs by eliminating the need for such MIPS eligible clinicians to submit data for both MIPS and their respective APMs, and to ensure that these eligible clinicians were not assessed in multiple ways on the same performance activities. We also believed that the APM scoring standard would encourage APM participation and support the goal of encouraging APM participants to better manage care for patients within their respective APM Entities by tying their MIPS performance scores together.

As we have gained experience in implementing the APM scoring standard, we have learned that it is infeasible to fully implement it as it was originally designed, as was discussed in the CY 2020 PFS final rule (84 FR 63007). Public comments on the CY 2020 revised APM scoring standard finalized in the CY 2020 PFS final rule (84 FR 63010), and most comments in response to the request for comments on APM scoring beyond 2020, made clear that the complexity of the APM scoring standard and its inflexibility in adapting to changes in APM participation and design have resulted in confusion and unintended additional burden for APM Entities and their participant MIPS eligible clinicians.

With this insight in mind, and with the goal of better aligning MIPS reporting rules for all MIPS eligible clinicians, including those in MIPS APMs, we proposed to terminate the APM scoring standard as described at § 414.1370, effective January 1 of the 2021 performance year, by amending that regulation accordingly.

We further proposed in the CY 2021 PFS proposed rule (85 FR 50285), effective January 1, 2021, to establish an APM Performance Pathway and scoring rules that would be available for MIPS reporting for MIPS eligible clinicians in MIPS APMs.

(b) APM Entity Groups

We proposed to terminate the APM scoring standard effective January 1, 2021, however, beginning with the 2021 performance period, we proposed to

retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with the 2021 performance period (85 FR 50303 through 50304). Therefore, we proposed to redesignate in part the regulation that describes APM Entity group determinations, from § 414.1370(e) to § 414.1317, and to title that section ''APM Entity Groups.''

We received the following comments on these proposals.

Comment: A few commenters stated support for allowing MIPS quality reporting at an individual or group level as well as the APM Entity level. Commenters believe that this approach would reward high performers within APM Entities and enable specialists to be scored on quality measures that reflect their area of practice.

Response: We thank commenters for their support and will continue to consider additional ways in which we can continue to support and encourage APM participation.

Comment: A few commenters supported the proposal but requested that we extend the waiver of the cost performance category to all APM participants in MIPS, as the cost-containment requirements of the APMs are equally applicable to all APM Entities, regardless of how they chose to participate in MIPS.

Response: In the CY 2017 Quality Payment Program final rule (81 FR 77256, 77265), for the APM scoring standard, we finalized at § 414.1370(g)(2) a policy to waive the cost performance category uner the waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs, and at section 1899(f) of the Act for the Medicare Shared Savings Program. In the CY 2021 PFS proposed rule (85 FR 50287), for the APP, we proposed to continue to waive the cost performance category under the same authorities, and we are finalizing this proposal in section IV.A.3.b. of this final rule. Upon further consideration, we recognize that the policy rationale for waiving the cost performance category is equally applicable to all APM Entities in MIPS APMs, regardless of whether an APM Entity chooses to participate in MIPS through the APP or through traditional MIPS reporting options. As we described in the CY 2017 Quality Payment Program final rule (81 FR 77256, 77265), and reiterated in the CY 2021 PFS proposed rule (85 FR 50287), we believe this use of waiver authority is justified for three reasons. First, APM Entities in MIPS APMs already are subject to cost performance assessment under their APMs, as the MIPS APM criteria would continue to include the assessment of participants based on cost. Second, MIPS APMs may measure cost performance in different ways than MIPS, for example, by basing cost on total cost of care, which measures a broader scope of cost or resource use than would necessarily be reflected in the narrower claims-based accountability standard under MIPS. Finally, MIPS APMs may attribute beneficiaries differently from MIPS for purposes of measuring cost, leading to an unpredictable degree of overlap between the sets of beneficiaries for whom the MIPS eligible clinicians would be responsible under their APM and under MIPS. We continue to believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population under the APM, it is necessary to give the APM Entity the ability to identify a single beneficiary population to prioritize in its cost-saving efforts so that the goals and evaluation associated with the APM are as clear and free of confounding factors as possible. With this flexibility, MIPS eligible clinicians who are attempting to strategically transform their respective practices would not jeopardize their ability to succeed in either MIPS or under the terms of their APM.

We believe the potentially conflicting or confounding incentives between the MIPS APMs and the MIPS cost performance category would still exist for APM Entities in MIPS APMs, regardless of which MIPS participation option an APM Entity chooses. Therefore, we will continue to waive the cost performance category for APM Entities in MIPS APMs under the waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs, and at section 1899(f) of the Act for the Medicare Shared Savings Program, and weight the cost performance category at zero percent of an APM Entity's final score.

In addition, because we proposed to no longer rely on quality measures reported to an APM, as is required under the existing APM scoring standard, we no longer believe that there is substantial risk of the MIPS final scores being inappropriately influenced by MIPS eligible clinicians moving into or out of APM Entities late in the performance year, which was the impetus for the full-TIN APM policy. Therefore, we proposed to end the full-TIN APM policy currently codified at § 414.1370(e)(1), which allows for an APM Entity group to include eligible clinicians on the Participation List in a full-TIN APM on December 31 of the MIPS Performance Period only if the APM is a full-TIN APM as defined at § 414.1305. We also proposed that MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the three snapshot dates (March 31, June 30, August 31), as well as December 31 during a performance period, beginning in the 2021 MIPS performance period, would be considered participants in an APM Entity group. As the proposals would eliminate the need for the term ''full TIN APM,'' we also proposed to delete the defined term ''full TIN APM'' from § 414.1305.

We did not receive any comments on this proposal.

After consideration of the comments we received, we are finalizing the proposed policy as proposed. In addition, for the reasons discussed in our response to comments above, we are adoptiong a final policy at § 414.1317(b)(2) to weight the cost performance category at zero percent for APM Entities in MIPS APMs.

(c) APM Entity Group Eligibility

In the absence of the APM scoring standard and mandatory reporting to MIPS through the APM Entity group, it would no longer be necessary to conduct low-volume threshold determinations at the APM Entity group level. Therefore, along with the termination of the APM scoring standard under § 414.1370, we also proposed to terminate, effective January 1, 2021, the use of APM Entity level low-volume threshold determinations and remove the term APM Entity group from the definition of the low-volume threshold at § 414.1305, with corresponding changes to applicability at § 414.1310(b)(1).

Going forward, we would apply the same rules for MIPS eligibility to APM participants as to other MIPS eligible clinicians. For example, if an eligible clinician who is a participant in a MIPS APM is below the low-volume threshold he or she would not be required to report to MIPS as an individual; however, if the group TIN of which that eligible clinician is a part is MIPS eligible and does report to MIPS, that eligible clinician would be treated as a MIPS eligible clinician for purposes of MIPS scoring and payment adjustments, and would receive the higher of the group score and any available APM Entity group score. Being a participant in an APM Entity that reports to MIPS would not confer MIPS eligibility to an eligible clinician who would otherwise be excluded from MIPS.

We did not receive public comments on this propsal and we are finalzing it as proposed.

(d) APM Entity Group Scoring

Consistent with our past approach under the APM scoring standard at § 414.1370(f), we proposed at § 414.1317(b) that the MIPS final score calculated for the APM Entity would be applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment would be applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

Similar to our past approach under the APM scoring standard at § 414.1370(g)(4)(ii) and (iii), as originally discussed and finalized in the CY 2017 Quality Payment Program final rule (81 FR 77268), we proposed at § 414.1317(b)(1) that in all cases where an APM Entity reports to MIPS, but a performance category's data submission cannot be made at the APM Entity level, each MIPS eligible clinician in the APM Entity group would be assigned the highest available score for that performance category (either the individual or TIN-level score), and the scores for all MIPS eligible clinicians in the APM Entity group would be averaged in order to calculate the APM Entity level performance category score. In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician would be assigned a null score when we calculate the APM Entity's performance category score.

Similar to our past approach under the APM scoring standard at § 414.1370(g)(1)(iv), we proposed at § 414.1317(b)(2) that for an APM Entity for which we calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, we would calculate an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b). Note that unlike § 414.1370(g)(1)(iv), proposed § 414.1317(b)(2) would not be limited to the quality performance category, but will apply to any performance category.

We did not receive public comments on these proposals and are finalzing as proposed.

(e) Reweighting Based on Extreme and Uncontrollable Circumstances for APM Entity Groups

Section 414.1380(c)(2)(i) allows for the submission of an application to CMS to request reweighting of one or more MIPS performance categories due to extreme and uncontrollable circumstances. We proposed that an APM Entity may submit such an application beginning with the 2020 performance period/2022 MIPS payment year, at § 414.1317(b)(3). The request for reweighting in the application would apply for all four MIPS performance categories and all MIPS eligible clinicians in the APM Entity group. If the request for reweighting is approved by CMS, this would result in MIPS eligible clinicians participating in the APM Entity being excepted from MIPS reporting requirements for the applicable performance period, and the APM Entity would receive a final score equal to the performance threshold. Such request for reweighting would be approved or denied in its entirety.

We considered allowing an APM Entity to submit an application to request reweighting for individual performance categories, but rejected this approach. As discussed in the CY 2021 PFS proposed rule (85 FR 50304, we believe the amount of complexity at the intersection of the various performance category submission and scoring requirements, submitter types, and exception applications for MIPS eligible clinicians could place a burden on these clinicians and their representatives to continually invest in understanding their shifting obligations under such an approach. Furthermore, operationalizing a policy where an APM Entity would have the ability to request and receive reweighting for one or more, but not all, performance categories would be prone to error. In addition, such a piecemeal approach to addressing extreme and uncontrollable circumstances likely would cause scoring delays that could result in CMS being unable to timely provide performance feedback and payment adjustment information to all MIPS eligible clinicians.

We also proposed at § 414.1317(b)(3)(i) that an APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

Due to the unique and complex relationship between an APM Entity and its individual participant MIPS eligible clinicians, we noted that we believe it is appropriate to offer an APM Entity the opportunity to apply for reweighting based on extreme and uncontrollable circumstances for all performance categories, including the Promoting Interoperability performance category, rather than collecting Promoting Interoperability hardship exception applications from each MIPS eligible clinician in the APM Entity group as is currently required. However, we believe that setting a 75 percent threshold for the Promoting Interoperability performance category is appropriate as a means of assuring that the request for reweighting is only granted in cases where absent the reweighting, it would be impossible to calculate a score for that performance category that is truly representative of the APM Entity group's performance. We proposed a 75 percent threshold because such threshold is consistent with the Promoting Interoperability performance category reweighting policy for groups of hospital-based MIPS eligible clinicians and non-patient facing MIPS eligible clinicians, which similarly could face an administrative burden in attempting to secure approvals for individual reweighting requests for each MIPS eligible clinician in such groups. We noted that we recognize that as a result of the variety of participation requirements of different APMs, APM Entity groups may be composed of a wide range of health care provider types and sites of service. We stated that we believe scoring an entire APM Entity as the result of a single MIPS eligible clinician's submission of data for the Promoting Interoperability performance category could place an extreme administrative burden on APM Entity groups, and could potentially create unintended consequences for APM participation decisions among MIPS eligible clinicians.

In addition, we proposed at § 414.1317(b)(3)(ii) that if CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories still would be reweighted for the APM Entity group notwithstanding the data submission. The data submission would not effectively void the request for reweighting and its approval. We proposed this policy because we do not believe it would be appropriate or desirable for an individual MIPS eligible clinician or for a group TIN with no direct affiliation with an APM Entity to accidentally override an APM Entity's application. This could happen if the MIPS eligible clinician or group TIN reports to MIPS either out of an abundance of caution or on behalf of a MIPS eligible clinician who is not in the APM Entity, but happens to share a billing TIN with an

eligible clinician who is in the APM Entity. We also recognized that there may be circumstances where an APM may require some form of quality reporting for purposes of the APM itself, such as is required for Shared Savings Program ACOs as described in the CY 2021 PFS proposed rule (85 FR 50233), but that in complying with such requirement an APM Entity may also be submitting quality performance category data that would result in scoring for purposes of MIPS when that APM Entity group would otherwise have been excepted from MIPS reporting.

We noted that under the proposal and the proposed changes to the MIPS scoring hierarchy, described in the CY 2021 PFS proposed rule (85 FR 50315), reporting done by a MIPS eligible clinician or group would result in a MIPS final score for only that MIPS eligible clinician or group, which may be used to determine a MIPS eligible clinician's payment adjustment.

To the extent that the proposed policies would constitute a change to the MIPS scoring or payment methodology for the 2022 MIPS payment adjustment after the start of the 2020 performance period, we noted that we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to establish these policies because of the PHE for COVID–19. We noted that we believe that the intersection of the 2020 APM scoring standard rules and the extreme and uncontrollable circumstances policies being put in place by APMs themselves in response to the PHE for COVID–19, such as the changes being proposed for participants in the Shared Savings Program, would make obtaining reweighting under MIPS based on extreme and uncontrollable circumstances unusually burdensome absent these proposed changes. For instance, the Shared Savings Program (85 FR 50239) will continue to require the submission of quality performance data by participating ACOs, and that data would be eligible to be used for MIPS quality scoring absent the proposal, which would have the result of not allowing Shared Savings Participants the option to take advantage of extreme and uncontrollable circumstances policies that are available to other MIPS eligible clinicians. This policy change is necessary to give participants in the Shared Savings Program the opportunity to request reweighting of the MIPS performance categories in the event that they believe the data reported for purposes of the Shared Savings Program do not adequately reflect the performance of the ACO Entity for purposes of MIPS quality performance category scoring.

The following is a summary of the comments we received and our responses.

Comment: Several commenters support our proposal to introduce APM Entity level requests for reweighting due to extreme and uncontrollable circumstances in light of the PHE for COVID–19.

Response: We appreciate the commenters for their support.

After consideration of the comments we received, we are finalzing this policy as proposed.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the 2023 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years. The scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. We are maintaining many of our scoring policies, focusing on only making proposals to maintain stability. Specifically, in the CY 2021 PFS proposed rule (85 FR 50305 through 50310), we proposed the following:

- To implement scoring flexibility for quality measures with specification or coding changes during the performance year.
- To implement benchmark and topped out scoring policies that are responsive to potential low reporting rates for the 2019 performance year due to the national PHE for COVID–19.
- To implement scoring for all administrative claims-based measures.
- To continue policies for scoring quality measures based on achievement as well as policies for measures that do not meet case minimum, data completeness requirements, or have a benchmark.
- To continue bonuses in the quality performance category.
- To continue improvement scoring of the quality performance category comparing clinicians to a 30 percent baseline score if clinicians scored 30 percent or less.

We did not propose changes to scoring policies for the cost, improvement activities and Promoting Interoperability performance categories.

We have maintained our approach that MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, comprised of their performance category scores, and calculated according to the final score methodology. We refer readers to § 414.1380 for general policies on scoring. We refer readers to section IV. A.3.c.(5) of this rule for the discussion to remove the APM scoring standard and to section IV.A.3.b. of this rule for information on the APM Performance Pathway scoring.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We referred readers to § 414.1380(b)(1) for our policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, and 84 FR 63011 through 63018). We proposed to maintain many policies finalized in prior years to retain stable scoring in MIPS with minimal new proposals as we transition to MVPs.

Please refer to section IV.A.3.c.(1)(c) of this rule for more information about our proposal to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians, which we are finalizing with implementation delayed until the 2022 performance period. Scoring policies applicable to CMS Web Interface as a collection type will be in effect in the 2021 performance period. In the 2022 performance period CMS Web Interface will be removed as a collection type.

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

We proposed to expand the list of reasons that a quality measure may be impacted during the performance period in addition to revising when we would allow scoring of the measure with a performance period truncation (to 9 months of data) or the complete suppression of the measure if 9 months of data are not available. We noted that we previously established policies to provide scoring flexibilities in instances in which changes to measures during the performance period have impacted clinicians' ability to submit the quality measures for the entire 12-month performance period because of an ICD–10 coding change or when there are clinical guideline changes when we believe continued adherence to the

guideline in the existing measure could result in patient harm, or otherwise provide misleading results and render the measure no longer comparable to the historic benchmark. Specifically, in the CY 2018 Quality Payment Program Final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD–10 coding changes during the performance period based only on the first 9 months of the 12-month performance period. We noted that we believe that 9 months of data is sufficient to assess performance when 12 months of data is not available. We finalized that we would publish a list of measures requiring a 9 months of data on the CMS website by October 1st of the performance period if technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period). We refer readers to § 414.1380(b)(1)(viii) for more on our policy for scoring flexibility for ICD–10 changes.

In the CY 2019 Quality Payment final rule (83 FR 59845 through 59847), we finalized policies beginning with the 2021 MIPS payment year to reduce the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise no longer be comparable to a historic benchmark. We refer readers to § 414.1380(b)(1)(vii)(A) for more information on the scoring flexibility policy.

We proposed, beginning with the 2021 performance period, a policy to truncate the performance period or suppress a quality measure if CMS determines that revised clinical guidelines, measure specifications or codes impact clinician's ability to submit information on the measure or may lead to potentially misleading results. Based on the timing of the changes to clinical guidelines, measure specifications or codes, we would assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we would suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted.

In addition to ICD–10 and clinical guideline changes, we noted that we believe that there may be instances when there are changes after the final approval of quality measures including changes to the measure specification, or updates to coding that may lead to misleading results. If there are no concerns with potential patient harm, we would like the ability to assess performance on the quality measure (not including the change) if we have sufficient data. Depending on the timing of the change during the performance period we would like to assess performance on the quality measure; we believe we can assess performance if we have 9 months of data and should suppress the measure if we have less than 9 months of data.

We will examine quality measures that are impacted by changes during the performance period to determine how the change may impact our ability to assess performance on the measure. Potential changes that may impact quality measures during the performance period include updates to clinical guidelines or measure specifications, such as revisions to medication lists, codes and clinical actions. For example, the introduction of a new drug class after the performance period began, would not be captured as numerator compliant by an existing measure specification but may meet the intent of the measure and its associated clinical actions. Assessment of clinician's performance on the measure would be hampered by the fact that the measure specification would not be able to be updated to collect information and assess performance related to use of the medication from the new drug class. As reflected at sections 1848(q)(2)(D)(1) and 1848(q)(2)(D)(1)(II)(cc) of the Act, quality measures adopted under MIPS, including substantive updates must be made through notice and comment rulemaking.

Additionally, we may examine a quality measure to determine if the change impacts the ability of clinicians to submit the measure, including the number of encounters a clinician may be able to submit, the number of clinicians who may be able to submit the measure, and the proportion of clinicians from a specialty who may be able to submit the measure. We would also assess if the change to a code would potentially lead to misleading results. For example, changes that impact the clinicians' ability to report a measure include changes to Common Procedural Technology (CPT) codes and the Healthcare Common Procedure Coding System (HCPCS) codes during the performance period, which may potentially produce misleading results. We believe that code changes that impact a clinician's ability to report a measure will be rare events, however, mid-year changes to CPT and HCPCS codes can be unanticipated when a clinician selects a quality measure and may introduce an additional burden if the clinician is unable to submit the quality measure.

When possible, we want an approach that allows us to score a quality measure even when there has been a change to the measure outside of the clinician's control during the performance period. We have finalized a policy that allows scoring on the first 9 months of data for a 12-month performance period data when there are ICD–10 code changes (82 FR 53714 through 53716). We assess performance on the first 9 months of data in the case of ICD–10 changes, which happen predictably in October on an annual basis, allowing us to truncate and remove the last quarter of the performance period from our assessment. However, as discussed in the CY 2021 PFS proposed rule (85 FR 50306 through 50307), we cannot anticipate when there will be a change to clinical guidelines, measure specifications, an inadvertent deletion, or revision of a code. These types of changes do not occur on an annual basis, and do not follow a predictable, consistent timeline. We become aware of changes to measures from feedback from clinicians, third parties and measure stewards. Updates to codes, which may not happen at a predictable time, may significantly impact how many cases a clinician can report and how a clinician performs on a measure. We want to account for instances such as coding changes during the performance period, in which scoring should be applied to the first 9 months of data from the performance period. If 9 consecutive months of data from the performance period is not available, we would have the ability to suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted.

Therefore, as noted in the CY 2021 PFS proposed rule (85 FR 50307 through 50308), we proposed beginning with the 2021 performance period, a policy to truncate the performance period or suppress a quality measure if CMS determines revised clinical guidelines, measure specifications or codes impact the clinician's ability to submit the measure or may lead to potentially misleading results. As proposed, we would maintain the flexibility to assess the measure on 9

consecutive months of data when available and would suppress the measure if 9 consecutive months of data are not available. We proposed that we would publish a list of measures requiring 9 months of data on the CMS website as soon as technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period).

Accordingly, we proposed to consolidate § 414.1380(b)(1)(vii)(A) and (b)(1)(viii) at § 414.1380(b)(1)(vii)(A). The consolidated paragraph would provide that for each submitted measure that is impacted by significant changes that CMS determines may result in patient harm or misleading results, performance on the measure is assessed based on data for 9 consecutive months of the applicable CY performance period. If such data are not available, the total available measure achievement points are reduced by 10 points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes'' means changes to codes (including ICD–10, CPT, and HCPCS), clinical guidelines, or measure specifications. We noted that we will publish a list of all measures scored under this paragraph (b)(1)(vii)(A) on the CMS website as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

We invited public comments on our proposal to truncate the performance period or suppress a quality measures if CMS determines that there are significant changes that occurred during the performance period. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported expanding policies for scoring measures with significant changes during the performance period that did not allow comparison to historical benchmarks.

Response: We thank commenters for their support.

Comment: One commenter recommended that CMS consider extending the scoring policies for measures with significant changes to include instances in which clinicians have difficulty obtaining 12 months of data, because a contract with a facility is modified during the performance period.

Response: The policies address instances in which there are significant changes to measures specifications or coding that do not permit any clinicians that selected the measure to submit data or other circumstances where a measure may result in patient harm or misleading results. It is not intended to address instances in which individual clinicians have difficulty obtaining and submitting data, while other clinicians are able to be measured accurately on the measure. The policy relates to changes to the measure, measure specifications or other changes that are outside of the clinicians' control and is applied to all clinicians. For individual clinicians, we have other scoring flexibilities for individuals unable to submit data, such as the ability to apply for reweighting of the quality performance category based on extreme and uncontrollable circumstances as described in section IV.A.3.d.(2)(b)(iv) of this final rule.

Comment: One commenter expressed concerns that depending on how CMS identifies substantive changes, the policy may result in the lack of scorable measures for some clinicians for a performance period and recommended working with measure stewards to determine the most appropriate course of action in each case to ensure the most accurate data is used. The commenter asked for clarification on the expected scale of the impact of this change, including how many measures are expected to be impacted, and how performance may shift for clinicians.

Response: The proposal was built on previously established policies in which CMS identifies the rare instances in which measures had significant changes during the performance period where adherence to the guideline of the existing measure or calculating the measure could result in patient harm or misleading results. The policy allows us to identify changes to measures that are outside of the control of clinicians. We often become aware of the changes from feedback from clinicians, third parties and measure stewards. We will continue to work with measure stewards on how the changes during the performance period impact measures. For example, we are concerned that due to changes in health care processes and use of hospital services during the PHE for COVID–19, there are significant changes to administrative claims data used to calculate measures, which may lead to misleading results. For purposes of § 414.1380(b)(1)(vii)(A), we would like to expand our definition so that ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. We do not anticipate that the proposed policy to identify mid-year changes to measures that require special scoring will result in no available and applicable measures for some clinicians.

Comment: One commenter did not support the suppression of scores for quality measures with significant changes during the performance period because they believed the policy added complexity to the program and recommended removing the quality measure and informing clinicians that they should select another measure. One commenter cautioned that allowing measures to be suppressed may inflate quality performance category scores and permit gaming because there was an incentive to submit measures that would be suppressed.

Response: We are concerned about program complexity but also realize that often clinicians select their measures in advance and establish workflows for the collection and reporting of data. We believe that expanding a previously finalized policy that truncates measures considered significantly impacted by ICD–10 coding changes during the performance period (82 FR 53714 through 53716) to include additional, significant changes to the measure outside of a clinician's control, will allow us to continue to use data that clinicians collected and reported. If data is available and does not cause patient harm or misleading results, our first priority is to utilize 9 months of data for scoring. We will attempt to make information available on a rolling basis about measures with significant changes; however, depending upon the timing, this might not allow sufficient time for clinicians to select another measure. When significant changes occur during the performance period, we believe that suppression of the measure or use of a truncated 9 months of data is appropriate, because clinicians are unaware of which measures will require the special scoring policies until after the performance period begins and all other submitted measures will be scored, we do not believe this will result in gaming or inflation of quality performance category scores.

Comment: A few commenters requested additional information about the approach to truncating the performance period of measures to 9 months of data. One commenter recommended that for measures that could only be scored on 9 months of data, that clinicians have the flexibility to select their 9-month reporting period. A few commenters asked if clinicians were able to submit 12 months of data for measures using a truncated 9 months of data, to be consistent with their reporting of other measures.

Commenters indicated that third party vendors would need to restructure reporting systems to limit reporting to 9 months of data.

Response: The policy to truncate the performance period to 9 months has been used when there are changes to measure coding, such as ICD–10 updates, in the final quarter of the performance period that are substantial enough to significantly impact the measure. We believe it is important to use data in these instances if there are no concerns that the 9 months of data could result in patient harm or misleading results. We would not allow clinicians to elect which 9 months of data to report because the truncation of the performance period occurs only if there is a change during the performance period that allows for 9 months of consecutive data; if there is a change during the performance period that does not allow for 9 months of data the measure will be suppressed. We believe that it is appropriate for clinicians to submit 9 months of data and recommend that clinicians work with third party intermediaries to allow submission of data.

Comment: One commenter indicated that the policy to truncate the performance period to 9 months of data would not be appropriate for quality measures affected by the increases of telehealth visits from March to August of 2020 because of the national PHE for COVID–19 and recommended greater flexibility in adjusting benchmarks for quality measures impacted by changes in patient access due to the national PHE in the 2020 performance year.

Response: We agree with the commenter that the policy to truncate the performance period can only be used if we have 9 consecutive months of data to assess performance. We will continue to monitor the impact of the use of telehealth and changes to clinical processes because of the national PHE for COVID–19, and work with measure stewards if they believe changes to clinical processes are significant enough to update clinical guidelines or trigger our scoring policies to suppress a measure. We continue to believe we should suppress a measure if the measure is impacted by significant changes that we determine may result in patient harm or misleading results. In section IV.A.3.d.(1)(b)(ii) of this final rule, we discuss our preference to use historical benchmarks when they are complete and reliable. If clinicians believe they are unable to submit quality measures for the 2020 performance period because of the national PHE for COVID–19, clinicians are allowed to submit an application for the reweighting of the quality performance category based on extreme and uncontrollable circumstances as described in section IV.A.3.d.(2)(b)(iv) of this final rule.

Comment: A few commenters urged caution in using less than a full year of measurement data. One commenter believes using only 9 months of data could potentially skew results. One commenter urged CMS to offer a review period and to work with measure stewards to determine the most appropriate course of action in each case to yield the most accurate data.

Response: We will continue to monitor how many measures are impacted by the scoring flexibility policies. Changes to measures specifications and coding often do not allow time for a public review period, however, we will continue to work with measure stewards when we believe that scoring flexibility polices are needed. As stated previously, we believe it is important to use data in these instances if there are no concerns that the 9 months of data could result in patient harm or misleading results.

Comment: One commenter requested clarification if policies to suppress or truncate data would be applied to all measures for the 2021 performance period.

Response: The policy will be applied to the 2021 performance period and beyond for each measure impacted by significant changes that CMS determines may result in patient harm or misleading results. To ensure that this includes all collection types, including administrative claims measures as well as all measures submitted by clinicians, we are modifying the proposal to update the finalized regulation text and consolidate § 414.1380(b)(1)(vii)(A) and (b)(1)(viii) at § 414.1380(b)(1)(vii)(A) to provide that for each measure that is submitted, if applicable, and impacted by significant changes that CMS determines may result in patient harm or misleading results, performance on the measure is assessed based on data for 9 consecutive months of the applicable CY performance period. If 9 months of data is not available, the measure will be suppressed.

After consideration of the public comments, we are finalizing our proposal with modification: We are finalizing the consolidation of § 414.1380(b)(1)(vii)(A) and (b)(1)(viii) at § 414.1380(b)(1)(vii)(A) to provide that for each measure that is submitted, if applicable, and impacted by significant changes, performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017, CY 2018, CY 2019, and CY 2020 Quality Payment Program final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, 83 FR 59841 through 59842, and 84 FR 63014 through 63016, respectively) for our previously established benchmarking policies.

In the CY 2017 QPP final rule (81 FR 77277 through 77282), we finalized that we would use performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or where we do not have comparable data from the baseline period, for which we would set the benchmarks using performance in the performance period. We defined the baseline period to be the 12-month CY that is 2 years prior to the performance period for the MIPS payment year. For example, for CY 2021 performance period, the baseline period would be CY 2019 which is 2 years prior to the CY 2021 performance period (81 FR 77277). Additionally, we further clarified that CMS can establish benchmarks either by the applicable baseline or performance period in the CY 2019 PFS final rule (83 FR 59842), where we finalized the terminology change amending § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

Because of the flexibility provided to MIPS eligible clinicians to allow for no data submission for the 2019

performance period (see 85 FR 19277 through 19278), we may not have had as representative of a sample of data as we would have had without the national PHE for COVID–19. Therefore, we revisited our benchmarking policy for the 2021 performance period. We anticipated that we may have a gap in our data due to potentially receiving fewer submissions for CY 2019 which could skew the benchmarking results, as the triggering of this policy no longer requires clinicians to submit data. We believed this gap in data could result in different distributions of scores from what we normally see, thus skewing the benchmarks when using CY 2019 baseline period for the CY 2021 performance period. As a result, we considered two benchmarking options for CY 2021 performance period.

We intended to use performance period benchmarks for the CY 2021 performance period in accordance with § 414.1380(b)(1)(ii). As discussed in the CY 2021 PFS proposed rule (85 FR 50307), this would mean that benchmarks for the CY 2021 performance period are based on the actual data submitted during the CY 2021 performance period. We noted that we believed that using performance period benchmarks for the year where we are facing gaps in baseline data will allow us to ensure that we continue to have reliable and accurate data. We recognized that this methodology would not allow clinicians to know the benchmarks ahead of the performance period, but we believe that using the most current information has the potential to provide more accurate results for benchmarking purposes for CY 2021 performance period and could capture any changes in care that have occurred as a result of the national PHE for COVID–19.

We sought feedback on the criteria for using data from the 2019 MIPS performance period to calculate CY 2021 benchmarks. As an alternative to performance period benchmarks we considered and requested stakeholder comments and feedback on utilizing the historic benchmarks from the 2020 MIPS performance period (which are based on submissions for CY 2018 MIPS performance period) for the CY 2021 performance period. We noted that we believe that this option would allow clinicians to continue to receive advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures for CY 2021 performance period. However, we remained concerned that utilizing outdated data could also potentially result in distributions of scores used for benchmarks that no longer reflect the standard of care.

We invited public comments on our intent to use performance period benchmarks for the CY 2021 performance period. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that CMS monitor and analyze to determine if the 2019 data is a representative sample based on the number of submissions for 2019 before deciding and finalizing which benchmarks should be used. A few commenters suggested that we see if there are statistically significant fewer submissions for CY 2019 than were received in previous performance periods that constitutes the need to use performance period benchmarks.

Response: Based on our analysis of 2019 submissions, we believe that we have sufficient data to calculate historical benchmarks and do not believe it is necessary to use performance period benchmarks. The analysis showed minimal to no impact due to the national PHE for COVID–19 policies for the eCQM and Part B claims collection types. Overall, we generally saw an increase in eCQM submissions. In addition, we know we have complete data from Part B claims collection types because that submission ended before the PHE. For the other collection types for 2021, the MIPS CQM and QCDR measures, we generally saw decreases in submissions, but the decreased submissions appear to have a modest distributional effect for most measures and is likely due to an increase in group reporting and the increase in eCQM submissions. The national PHE for COVID–19 E/U circumstances policy led to only a slight increase in the number of clinicians not engaged with MIPS in 2019 compared to 2018 submission data.

Comment: Several commenters opposed the use of 2021 performance period benchmarks as this would not allow clinicians to have referenceable benchmarks as a guide to predict their scores or set performance goals or priorities, making it difficult to determine performance improvement opportunities and preferred the use of historical benchmarks from 2019 data. Several commenters did not support holding clinicians accountable for performance against a benchmark that would not be set until after the performance period is closed as the use of performance period benchmarks would burden clinicians by not providing time to understand how performance compares to benchmarks and could lead to lower performance and MIPS scores. Several commenters encouraged CMS to publish a benchmark file to provide guidance to evaluate and strategize reporting. A few clinicians stated that the use of performance period benchmarks would burden clinicians by not providing time to understand how performance compares to benchmarks and could lead to a decrease in performance and MIPS scores. A few commenters specifically supported using historical benchmarks from the 2019 MIPS performance period data over utilizing 2018 data for benchmarks because the 2019 performance period provides more recent data.

Additionally, one commenter stated that using performance period benchmarks would limit EHR vendors' ability to provide timely scoring feedback and insight into performance. One commenter suggested that CMS use 2019 benchmarks for 2021 performance and to limit the performance period to the months at the end of 2021 not impacted by the national PHE for COVID–19 to allow for comparison of data not influenced by the national PHE for COVID–19 in 2019 to 2021.

Response: We agree that providing a historical benchmark for the quality performance category allows MIPS eligible clinicians to know quality performance category benchmarks in advance. We believe there is value in the advance notice for quality performance measures so that MIPS eligible clinicians can benchmark themselves for quality measures when historical data is available. We agree with commenters that quality benchmarks should be made public and should be known in advance when possible so that MIPS eligible clinicians can understand how they will be measured and to not limit vendors from providing timely feedback and insight into performance. We will continue to rely on historical benchmarks for CY 2021 since data from CY 2019 has become available and is representative and comparable. We will continue to monitor the impact of the national PHE for COVID–19 on data in CY 2020 and CY 2021. The historical benchmarks based on CY 2019 data will be available prior to the CY 2021 performance period at *qpp.cms.gov*.

Comment: Many commenters supported the use of 2021 performance period benchmarks since they are based on current information that can provide accurate benchmarks from data that are reliable, accurate, complete, and representative of performance in 2021. The commenters expressed support given that performance period benchmarks capture any changes in care

due to the national PHE for COVID–19 and avoid unfairly penalizing practices for variations in performance compared to data from prior to the national PHE for COVID–19.

Response: Based on our analysis of the 2019 data, we believe that the data is reliable, complete, or representative and no longer believe we need to rely on performance period benchmarks. We realize there may be a risk for some measures that performance in CY 2021 might differ from CY 2019 given the automatic extreme and uncontrollable circumstances policy for CY 2019 quality performance category in response to the national PHE for COVID–19 (85 FR 19277 through 19278). We are continuing to evaluate the effects of the national PHE for COVID–19 on clinicians and will take this comment into consideration for the future, but we also understand and have previously stated, that there are benefits to knowing the benchmark target in advance and believe there is value to clinicians in having historical benchmarks. We believe there is more value in providing advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures, provided that historical data is available.

Comment: Several commenters opposed the use of performance period benchmarks and supported the alternative to use historical benchmarks based on 2018 MIPS performance data to continue to receive advance notice of benchmarking targets, allow clinicians to understand how they are performing in real-time compared to the 2018 benchmarks, provide a degree of certainty, and help clinicians prepare in advance for selecting measures based on data that is not impacted by the national PHE for COVID–19. A few commenters recommended using historical benchmarks from 2018 data for the 2021 performance year if the participation rate dropped significantly from 2018 to 2019. A few commenters stated that CEHRT vendors rely on benchmarks to set dashboards and reports and having benchmarks from 2018 would allow developers to provide accurate information to clinicians. A few commenters stated that the data from 2019 might not be inclusive because of the extreme and uncontrollable circumstance policy for the national PHE for COVID–19 and performance period benchmarks will make it difficult for clinicians to predict how they will score. One commenter suggested the use of CY 2020 quality data as a baseline for benchmarking for CY 2021. One commenter suggested calculating benchmarks by combining 2017, 2018, and 2019 data to provide a larger sample to address concerns around skewed data while still providing target information.

Response: Based on our 2019 data analysis, we believe we have sufficient data to reliably generate historical benchmarks for CY 2021 and we will not need to rely on 2018 benchmarks to provide a known target for benchmarking. Using historical benchmarks based on the reliable and complete data from 2019 will allow us to provide benchmarks based on more recent data in advance for clinicians to prepare and since the data from 2019 is usable, representative, and more recent, we do not believe it necessary to use data from 2018 to create benchmarks for CY 2021, as it would be more out of data than data from 2019. Using the data from 2019, CEHRT vendors remain able to rely on the benchmarks for CY 2021 to set dashboards and reports to provide accurate information to clinicians. Additionally, we do not believe we need to combine benchmarks across years to create a reliable benchmark.

Comment: Several commenters suggested that we calculate two benchmarks, one historical and one performance period, and then have CMS use the more favorable of the two benchmarks for each measure. The commenters suggested this approach to provide baseline information to guide measure selection and advance notice to clinicians on possible benchmarks while considering the impact of the national PHE for COVID–19 and having complete, reliable data. One commenter suggested calculating both 2019 and 2020 performance year measure benchmarks and using the lower benchmark for each quality measure since CMS already calculated this data and will allow for comparing scores given the impact of the national PHE for COVID–19. One commenter recommended that CMS use CY 2019 data to publish a benchmark file and then score measures based on the average of 2021 and 2019 data. One commenter suggested setting a threshold to assess change in benchmarks and if the change threshold is not exceeded, a performance period benchmark would be appropriate. If change above the set threshold occurred, the historical benchmark would be used.

Response: Based on our 2019 data analysis, we can use historical benchmarks for CY 2021 that are complete and reliable and do not believe that we need to create two benchmarks or use an average of 2 years of data to create a benchmark. The data we received for CY 2019 is robust as we only saw a slight increase in the number of clinicians not engaged with MIPS in CY 2019 compared to CY 2018 submission data. This allows us to provide benchmarks in advance for clinicians to have baseline information to guide measure selection and gives advance notice to clinicians on benchmarks. The benchmarks based on CY 2019 data will be available prior to the CY 2021 performance period at *qpp.cms.gov*.

Comment: Several commenters recommended that CMS consider the impacts that the PHE for COVID–19 will have on participation and data from 2019, 2020, and potentially 2021 when setting future benchmarks. Commenters stated that the national PHE for COVID–19 will continue to disrupt patient volume, case mix, and patient outcomes, making data incomparable when comparing years impacted by the national PHE for COVID–19 to prior years without impact. A few commenters requested CMS to take major changes in care, including disruptions in the delivery of medical services, into account when comparing data from year to year. A few commenters suggested that CMS compute benchmarks with 2018, 2019, and 2020 data separately to understand the impact of the PHE on quality measures. One commenter stated that due to the removal of telehealth exclusion language from select measure specifications, data will not be comparable and will no longer be reliable for measures in the future.

Response: For performance year 2020, we continue to offer the extreme and uncontrollable circumstances policy in response to the national PHE for COVID–19, allowing clinicians to submit an application for the reweighting of the quality performance category based as described in section IV.A.3.d.(2)(b)(iv) of this final rule. We will continue to monitor the impacts of the national PHE for COVID–19 on data comparability, including due to the removal of telehealth exclusion language from select measure specifications, and will incorporate changes and offer flexibilities through future rulemaking cycles, as necessary, to account for changes in care delivery. Benchmarks from CY 2018 data have already been released publicly and benchmarks from CY 2019 data will be released prior to the start of CY 2021. Benchmarks from CY 2020 data will be released once the data is available. Those benchmarks will be available at *qpp.cms.gov*.

After consideration of the public comments, we are not finalizing our intent to use performance period benchmarks for the CY 2021

performance period and will use historical benchmarks for CY 2021 based on the 2019 data.

(iii) Minimum Case Requirements

In the CY 2017 Quality Payment program final rule (81 FR 77287 to 77289), we finalized that we will use 20 cases as the case minimum for all quality measures, with the exception of the hospital-wide readmission measure which has a minimum of 200 cases. As proposed in Table Group A within Appendix 1, the hospital-wide readmission measure is replacing the all-cause readmission measure and an additional administrative claims-based measure for hip/knee complications is being added to the program. In the case of the hospital-wide readmission measure, the case minimum will remain the same at 200 cases and will only apply to groups. For the new hip/knee complications measure, a case minimum of 25 is proposed and is applicable for individuals and groups. As noted in the CY 2021 PFS proposed rule (85 FR 50308), we proposed to amend § 414.1380(b)(1)(i) to clarify how administrative claims measures are scored. We proposed to amend § 414.1380(b)(1)(iii) to reflect that, except for administrative claims measures, the minimum case requirement is 20 cases. For each administrative claims-based measure, the minimum case requirement is specified in the annual list of MIPS measures.

We invited public comments on our proposal to amend § 414.1380(b)(1)(i) to clarify how administrative claims measures are scored and amend § 414.1380(b)(1)(iii) to reflect that, except for administrative claims measures, the minimum case requirement is 20 cases. The following is a summary of the comments we received and our responses.

Comment: One commenter did not support the proposal to define the minimum case requirement for administrative claims measures in the annual list of MIPS measures. One commenter recommends that CMS maintain the current regulatory process of limiting such requirements to amounts specifically listed in regulation (for example, for non-administrative claims measures, the minimum case requirement is 20 cases) to minimize negative impact in program compliance and to limit additional changes in an already nuanced quality reporting program.

Response: While we understand the commenter's concern regarding additional annual updates, we believe providing the specific minimum case requirements for administrative claims measures in the annual list of MIPS measures allows these measures to be reliably scored based on the case minimum specific to each measure. Based on the specifications, administrative claims measures may require a case minimum that is an exception to the 20 cases otherwise required. Any further changes in the case minimum requirement would be considered substantial and would go through rule making. Additionally, this exception is for administrative claims measures, which do not require reporting and are based on claims data we receive.

Comment: One commenter stated that a sample of 25 cases is insufficient to provide meaningful data for the newly added hip/knee complications measure.

Response: While we understand the commenter's concern about the proposed case minimum for the new hip/knee complications measure, we selected a minimum case count of 25 to ensure a measure result is available for most eligible clinicians and eligible clinician groups while maintaining measure reliability. We believe that for this measure, a minimum case count of 25 cases demonstrates reliability results consistent with standards of other measures within MIPS. We refer readers to Table Group A of Appendix 1 of this rule for discussion on new individual MIPS quality measures proposed for the 2023 MIPS payment year and future years.

After consideration of the public comments, we are finalizing our proposal as proposed.

(iv) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1)(i) for more details on our policies for scoring performance on quality measures (81 FR 77276 through 77307, 82 FR 53694 through 53701, 83 FR 59841 through 59856, and 84 FR 63011 through 63019).

(A) Scoring Measures Based on Achievement

We previously established at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable) for the 2019 through 2022 MIPS payment years. MIPS eligible clinicians receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77282), we established that measures with a benchmark based on the performance period (rather than on the baseline period) would continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, we stated that we would revisit the 3-point floor in future years.

For the 2023 MIPS payment year, we proposed to again apply a 3-point floor for each measure that can be reliably scored against the benchmark. As we move towards the MVP framework discussed the CY 2021 PFS proposed rule (85 FR 50308), we anticipated we will be able to score quality measures from 1 to 10 for measures in MVPs and as such will revisit and possibly remove the 3-point floor for traditional MIPS in future years. As a result, we discussed that we would wait until there is further policy development under the MVP framework before proposing to remove the 3-point floor. Accordingly, in the CY 2021 PFS proposed rule (85 FR 50308), we proposed to revise § 414.1380(b)(1)(i) to remove the years 2019 through 2022 and adding in its place the years 2019 through 2023 to provide that for the 2019 through 2023 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340.

We invited public comments on our proposal to again apply a 3-point floor for each measure that can be reliably scored against a benchmark for the MIPS 2023 payment year. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to continue the 3-point floor for each measure that can be reliably scored against a benchmark.

Response: We thank the commenters for their support.

Comment: One commenter recommended adopting a 5-point floor for each measure that can be reliably scored against a benchmark to help mitigate the disruptive effects of the PHE and to provide incentives for clinicians to report measures. A few commenters recommended adopting a universal scoring floor of 5 points to mitigate the disruptive effects of the national PHE for COVID–19 on benchmarks while incentivizing clinicians to report measures that

historically lack a benchmark and would increase use of under-reported measures and incentivize clinicians to report instead of opting out.

Response: We appreciate the commenter's concern. We do not want to mask performance with a floor above 3 points. Clinicians will know in advance what the benchmarks are, and we believe that the 3-point floor provides protection for clinicians.

After consideration of the public comments, we are finalizing our proposal as proposed.

(B) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We refer readers to § 414.1380(b)(1)(i)(A) and (B) for more on our scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement (84 FR 63012).

In the 2017 QPP final rule (81 FR 77288) and the 2018 QPP final rule (82 FR 53727), we identified ''classes of measures'' which were intended to characterize measures for the ease of discussion. Class 1 measures are measures that can be scored based on performance because they have a benchmark, meet the case minimum and data completeness requirements. Class 2 measures are measures that cannot be scored based on performance because they do not have a benchmark or do not meet the case minimum which is generally 20 cases. Class 3 measures are measures that do not meet the data completeness requirement. We also noted that policies for Class 2 and Class 3 measures would not apply to measures submitted with the CMS Web Interface or administrative claims-based measures.

We did not propose to modify how we score these measures within MIPS, as we consider policies for transitioning to MVPs. For class 2 measures, for the 2023 MIPS payment year, we proposed to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark, due to fewer than 20 individual clinicians or groups adequately reporting the measure, or meet the case minimum requirement. Accordingly, in the CY 2021 PFS proposed rule (85 FR 50308 through 50309), we proposed to revise § 414.1380(b)(1)(i)(A)(*1*) to remove the years 2019 through 2022 and add in its place the years 2019 through 2023 to provide that except as provided in paragraph (b)(1)(i)(A)(*2*) (which relates to CMS Web Interface measures and administrative claims-based measures), for the 2019 through 2023 MIPS payment years, MIPS eligible clinicians would receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

We invited public comments on our proposal to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement for the MIPS 2023 payment year. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the continuation of the policies as proposed.

Response: We appreciate the commenter for their support.

Comment: A few commenters did not support the proposal to continue the 3 measure achievement points for measures without a benchmark because the commenters believed that the policy provides a disincentive to submit more specialized measures and recommended that CMS provide bonus points for submitting measures without a benchmark.

Response: We recognize the commenters' concerns regarding the assignment of 3 points to measures without a benchmark. We are continuing to evaluate our approach to scoring measures without a benchmark and will take these comments into consideration for the future.

After consideration of the public comments, we are finalizing our proposal as proposed.

A summary of the policies for the CY 2021 MIPS performance period is provided in Table 49.

TABLE 49: Quality Performance Category: Scoring Policies for the CY 2021 MIPS Performance Period*

Measure type	Description	Scoring rule for Traditional MIPS
Class 1	Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Meets case minimum; and (3) Meets the data completeness standard (generally 70 percent for 2021.)**	For the 2021 MIPS performance period: 3 to 10 measure achievement points based on performance compared to the benchmark.
Class 2	For the 2020 MIPS performance period: Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark; and (2) Meets case minimum.	For the 2021 MIPS performance period: 3 measure achievement points.
Class 3	Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum.	Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero points for this measure. Small practices will continue to receive 3 points.

*The Class 2 and 3 measure scoring policies are not applicable to CMS Web Interface measures or administrative claims-based measures.
**We refer readers to § 414.1335(a)(3) for our policy on data completeness.

(v) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to § 414.1380(b)(1)(iv) for our previously finalized policies regarding the identification of topped out measures and § 414.1380(b)(1)(iv)(B) for our finalized policies regarding the scoring of topped out measures. Under § 414.1380(b)(1)(iv), we will identify topped out measures in the benchmarks published for each Quality Payment Program year. Under § 414.1380(b)(1)(iv)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727).

We noted in the CY 2021 PFS proposed rule (85 FR 50307) that we intended to use performance period benchmarks for the 2021 MIPS performance period, which would mean we would not be able to publish measures that are topped out prior to the 2021 MIPS performance period. As discussed in that proposed rule (85 FR 50309), this also means we would not be able to identify those that have been topped-out for 2 or more consecutive years for purposes of the topped out scoring of 7 measure achievement points. We noted that we believe it is still important to retain a topped-out scoring cap of 7 measure achievement points so that clinicians have incentives to pick alternate measures that are not topped out. We also noted that a measure may not always be topped out and we believe that if a measure is not topped out in the 2021 performance period benchmark, then it should have the ability to achieve up to 10 measure achievement points.

Therefore, for the 2021 MIPS performance period, as an exception from the general rule at § 414.1380(b)(1)(iv)(B), we proposed at § 414.1380(b)(1)(iv)(B)(*1*) to apply the 7 measures achievement point cap to measures that meet the following two criteria. The first criterion would be that the measures have been topped out for 2 or more periods based on the published 2020 MIPS performance period historical benchmarks (which are based on submissions for the 2018 MIPS performance period). The second criterion would be the measures remain topped out after the 2021 MIPS performance period benchmarks have been calculated. We noted that we believe these two criteria collectively would provide clinicians the information to know prior to the 2021 MIPS performance period which measures would have the topped-out scoring applied but would also account for the scenario where a measure is no longer topped out. We would not limit the number of measure achievement points for measures that have not been topped out for at least 2 years as published in the 2020 MIPS performance period historical benchmarks.

We invited public comments on our proposal to apply the 7 measures achievement point cap to measures that meet the two criteria. The following is a summary of the comments we received and our responses.

Comment: Several commenters do not support the proposal to apply the scoring cap of 7 achievement points for the 2021 performance period for measures that are found to be topped out and based this rationale on the thinking that the cap would apply to topped out measures for 2 or more consecutive years, including the 2021 MIPS performance period benchmarks. A few commenters discussed concerns over not knowing which measures will have the cap prior to the 2021 performance period and could put clinicians at risk of inadvertently reporting on measures with topped out

benchmarks, resulting in a capped score for the measure.

Response: We appreciate the commenters' responses for this proposal. As discussed in section IV.A.3.d.(1)(b)(ii) of this rule, we no longer intend to use performance period benchmarks and will use historical benchmarks for CY 2021. This allows us to provide benchmarks in advance for clinicians to have baseline information to guide measure selection. Because we are using historical benchmarks, we no longer need an exception to identify topped out measures, instead we will follow our normal topped out lifecycle process.

Comment: A few commenters requested that CMS suspend the topped-out measure scoring cap for the 2021 MIPS performance period due to the national PHE for COVID–19 and since many topped-out measures remain the most meaningful measures on which certain clinicians can report.

Response: We appreciate the commenters' concern about the scoring cap for topped out measures. As MIPS is a performance-based program, we do not believe that MIPS eligible clinicians electing to report topped out measures should be able to receive the same maximum score as other measures that demonstrate variations in performance and room for improvement. We therefore continue to believe it necessary to maintain the 7-point cap for measures identified as topped out. Additionally, please refer to *qpp.cms.gov/about/covid19* for our national PHE for COVID–19 response and flexibilities provided within QPP.

Comment: Several commenters supported the proposed criteria for determining which measures should have the 7-point cap applied in 2021 performance year based on the use of performance period benchmarks as it provides important protections for clinicians given the impact of the national PHE for COVID–19.

Response: We appreciated the commenters for their support for this policy based on the intended use of the performance period benchmarks, but note that we are not finalizing the use of performance period benchmarks policy as discussed in section IV.A.3.d.(1)(b)(ii) of this rule.

After consideration of public comments, we are not finalizing our proposal to create an exception from the general rule at § 414.1380(b)(1)(iv)(B) that we had proposed at § 414.1380(b)(1)(iv)(B)(*1*). Instead, we will continue our policy that the 7-point cap will be applied to measures (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years, beginning in the second year the measure is identified to be topped out.

(vi) Incentives To Report High-Priority Measures

We refer readers to § 414.1380(b)(1)(v)(A) for our previously finalized policies regarding incentives to report high priority measures. In the CY 2017 Quality Payment Program final rule (81 FR 77293), we established the scoring policies for high priority measure bonus points to encourage the selection of additional high-priority and outcome measures that impact beneficiaries and were closely aligned to our measurement goals. In the CY 2019 PFS final rule (83 FR 59850), we discontinued awarding measure bonus points to CMS Web Interface reporters for reporting high priority measures since CMS Web Interface reporters have no choice in measures.

We stated in the CY 2019 PFS proposed and final rules (83 FR 35950, 59851) that as part of our move towards fully implementing high value measures, we believe that bonus points for high priority measures for all collection types may no longer be needed, and as a result, we intended to consider in future rulemaking whether to modify our scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year. We noted in the CY 2019 PFS final rule (83 FR 59851) that measure bonus points were created as transition policies which were not meant to continue through the life of the program. We believe with the finalized framework for transforming MIPS through MVPs (84 FR 62948), we will find ways in the future to emphasize high priority measures without needing to incentivize with bonus points. As a result, we noted that we would wait until there is further policy development under the MVP framework before proposing to remove our policy of assigning bonus points for high priority measures.

As noted in the CY 2021 PFS proposed rule (85 FR 50309 through 50310), we proposed to maintain the cap on measure points for reporting high priority measures for the 2023 MIPS payment year. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(A)(*1*)(*ii*) to remove the years 2019 through 2022 and adding in its place the years 2019 through 2023 to provide that through the 2023 MIPS payment year, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

We invited public comments on our proposal to maintain the cap on measure points for reporting high priority measures for the 2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to continue the high priority bonus. Commenters expressed the belief that these bonuses can help clinicians meet the performance threshold.

Response: We thank the commenters for their support.

Comment: One commenter did not support our stated intention to phase out high priority measure bonus points in the future because commenter believes these bonuses are important to ensure benchmarks are established for these high priority measures through incentivizing reporting.

Response: We appreciate the commenter's concerns and will take their recommendations into consideration for the future. We envision that the progression of the MIPS program under the MVP framework will allow us to remove some of the scoring complexity associated with the MIPS program. We anticipate that removing bonuses would be part of this framework. We also understand the interest in being as flexible as possible in awarding clinicians for supporting the goals of the program such as reporting high priority measures and creating benchmarks. While bonuses do not directly affect the calculation of benchmarks, we will continue to consider the best ways to support our goals in future rulemaking.

After consideration of the public comments, we are finalizing our proposal as proposed.

(vii) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT. In the CY 2017 Quality Payment Program final rule (81 FR 77297), we established the measure bonus point and bonus cap for using CEHRT for end-to-end reporting. We refer readers to § 414.1380(b)(1)(v)(B) for our previously finalized policies regarding measure bonus points for end-to-end electronic reporting. We believe that with the framework for transforming MIPS through MVPs discussed in the CY 2020 PFS proposed rule (84 FR 40739) and the CY 2021 PFS proposed rule (85 FR 50279 through 50285), we will find ways to incorporate digital measures without needing to incentivize end-to-end reporting with

bonus points. In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged stakeholders to consider electronically specifying their quality measures as eCQMs, to encourage clinicians and groups to move towards the utilization of electronic reporting. As noted in the CY 2019 PFS final rule (83 FR 59851), bonus points were created as transition policies which were not meant to continue through the life of the program. As a result, we noted that we would wait until there is further policy development under the finalized MVP framework (84 FR 62948) before proposing to remove our policy of assigning bonus points for end-to-end electronic reporting.

As noted in the CY 2021 PFS proposed rule (85 FR 50310), we proposed to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2023 MIPS payment year. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(B)(*1*)(*i*) to remove the years 2019 through 2022 and add in its place the years 2019 through 2023 to provide that for the 2019 through 2023 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

We invited public comments on our proposal to maintain the cap on measure bonus points for end-to-end electronic reporting for the 2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported and urged CMS to continue the bonus for end-to-end reporting using CEHRT because it would drive electronic reporting and maintain stability in the program.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal as proposed.

(viii) Improvement Scoring for the MIPS Quality Performance Category Percent Score

We refer readers to § 414.1380(b)(1)(vi)(C)(*4*) for more on our policy stating that for the 2020 through 2022 payment years, for the purpose of improvement scoring, we will assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

As noted in the CY 2021 PFS proposed rule (85 FR 50310), we proposed to continue our previously established policy for improvement scoring for the 2023 MIPS payment years and to revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 through 2022 MIPS payment year'' and adding in its place the phrase ''2020 through 2023 MIPS payment years'' to indicate that for each MIPS payment year through 2023, we will assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. Specifically, for the 2023 MIPS payment year, we would compare the MIPS eligible clinician's quality performance category achievement percent score for the 2021 MIPS performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance score less than or equal to 30 percent for the 2020 MIPS performance period.

We invited public comments on our proposal to assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year for the 2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for improvement scoring for the quality performance category because it better rewards high quality performers and promotes strategic priorities of CMS.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal as proposed.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 and CY 2020 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, respectively). In the CY 2021 PFS proposed rule (85 FR 50310 through 50315), we proposed to continue the complex patient bonus for the 2023 MIPS payment year, and we also proposed to modify the complex patient bonus for the 2022 MIPS payment year as established in prior rulemaking due to the PHE for COVID–19. In addition, we proposed performance category redistribution policies for the 2023, 2024, and future MIPS payment years.

(a) Complex Patient Bonus

(i) Background

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our MIPS scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS; and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act)) (Pub. L. 113–185, enacted on October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we established at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). In subsequent rulemaking, we continued the complex patient bonus at § 414.1380(c)(3) for the 2021 and 2022 MIPS payment years (83 FR 59870 and 84 FR 63023). We refer readers to these final rules for additional details on the background, statutory authority, policy rationale, and calculation of the complex patient bonus.

We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. The overall goal, when considering a bonus for complex patients, is two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We used

the term ''patient complexity'' to take into account a multitude of factors that describe and have an impact on patient health outcomes; such factors include the health status and medical conditions of patients, as well as social risk factors. We believe that as the number and intensity of these factors increase for a single patient, the patient may require more services, more clinician focus, and more resources in order to achieve health outcomes that are similar to those who have fewer factors. In developing the policy for the complex patient bonus, we assessed whether there was a MIPS performance discrepancy by patient complexity using two well-established indicators in the Medicare program: Medical complexity as measured through Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients that are dually eligible for Medicare and Medicaid (82 FR 53771 through 53776).

(ii) Complex Patient Bonus for the 2023 MIPS Payment Year

As discussed in the CY 2021 PFS proposed rule (85 FR 50310), we intended the complex patient bonus as a short-term solution to address the impact patient complexity may have on MIPS scoring. However, we noted that we currently do not believe we have sufficient information available to develop a long-term solution to account for patient risk factors in MIPS that we could include as a proposal for the 2023 MIPS payment year. In the CY 2020 PFS proposed and final rules, we considered whether newly available data from the Quality Payment Program still supported the complex patient bonus at the final score level. More specifically, within the data analysis, we did not observe a consistent linear relationship for any reporting type or complexity measure, HCC risk score or dual eligible status (84 FR 40793 through 40795 and 84 FR 63021 through 63023). However, we only have a few years of data and believe that more recent data may bring different results than the findings we explained in detail in the CY 2020 PFS final rule. We refer readers to the CY 2020 PFS final rule for further details on the methodology and findings (84 FR 63021 through 63023).

As stated previously in this final rule, section 1848(q)(1)(G) of the Act requires us to take into account the relevant studies conducted under section 2(d) of the IMPACT Act and, as appropriate, other information, including information collected before completion of such studies and recommendations. ASPE completed its first report in December 2016, which examined the effect of individuals' socioeconomic status on quality, resource use, and other measures under the Medicare program, and included analyses of the effects of Medicare's current value-based payment programs on clinicians serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. We also noted, in the CY 2020 PFS final rule, that a second ASPE report on social risk factors within CMS value-based purchasing programs was expected. This second report, Social Risk and Performance in Medicare's Value-Based Purchasing Programs, was publicly released in June 2020, which builds on the analyses included in the initial report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs.[126] More specifically, the report has a 3-pronged strategy approach to measure and report quality; to set high, fair quality standards; and to reward and support better outcomes for beneficiaries with social risk. As a part of this 3-pronged strategy, the report supports the use of the complex patient bonus in MIPS, explaining that it is well supported because this policy gives additional points to clinicians who treat patients with high social risk factors and does not lower the standard of care. Further, the report suggested that CMS should not include the complex patient bonus within the final score that is publicly reported to ensure that patients can see the true clinician performance. As we continue to review the findings from the report, we intend to consider its recommendations, along with any updated data that would become available, for future rulemaking. Hence, based on our data analysis from the CY 2020 PFS final rule (84 FR 63022) and the lack of currently available additional data sources, for the 2021 MIPS performance period/2023 MIPS payment year, we proposed to continue the complex patient bonus without any modifications (as finalized for the 2020 MIPS performance period/2022 MIPS payment year) and to revise § 414.1380(c)(3) accordingly. We noted that we plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify longer term policy solutions that achieve the goals of attaining health equity for all beneficiaries, minimizing unintended consequences, and would propose modifications to the complex patient bonus in future rulemaking as appropriate.

We invited public comments on our proposal to continue the complex patient bonus for the 2021 MIPS performance period/2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to continue the complex patient bonus of up to 5 points for the 2021 MIPS performance period/2023 MIPS payment year. Another commenter supported the complex patient bonus but requested that we increase the complex patient bonus.

Response: We thank the commenters for their support to maintain the complex patient bonus for the 2021 MIPS performance period/2023 MIPS payment year. We plan to review available information, including any updated data, in future years to determine if it is appropriate to modify our approach to adjusting for social risk factors.

Comment: Many commenters encouraged CMS to finalize the proposed policy, discussed in the CY 2021 PFS proposed rule (85 FR 50311), of doubling the complex patient bonus for the CY 2020 performance period, and to continue doubling the complex patient bonus into the CY 2021 performance period, because the impact of the national PHE for COVID–19 will likely continue, as well as the associated increased complexity due to COVID–19.

Response: We understand that both direct and indirect impacts of the PHE for COVID–19 will likely continue into CY 2021. We will continue to assess and better understand the implications of the national PHE of COVID–19 on care delivery and complex patient care during 2021 and will consider whether to make any policy changes in future rulemaking. At this time, we continue to offer the application-based extreme and uncontrollable circumstances policy for CY 2021, as referenced in section IV.A.3.d.(2)(b)(iv)(B) of this final rule, and we believe we do not need to continue to double the complex patient bonus for the 2021 performance period/2023 MIPS payment year, although we intend to reevaluate after we gather more data and learn more about both the direct and indirect impacts of the PHE for COVID–19. We will continue to assess our complex patient bonus policy regarding both the value of the points and the calculation methodology and ensure that we do not risk artificially increasing MIPS final scores while providing enough flexibility to clinicians to account for increased patient complexity.

[126] ASPE. Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 29 2020. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

Comment: A few commenters pointed out perceived limitations in the use of the HCC risk score in calculating the complex patient bonus. More specifically, they believed that the existing methodology does not fully and appropriately capture the clinical and social complexity of patients and encouraged CMS to find more appropriate and long-term solutions. A few commenters suggested that CMS consider other medical and social risk factors outside of what is already captured in the HCC and dual-eligible status, when determining patient complexity. Another commenter requested that CMS develop an alternative applicable to all clinician types. One commenter suggested that CMS include ICD–10 Z codes, such as Z590.0 homelessness, Z65.0 unemployed, or Z59.5 extreme poverty to capture additional social risk factors.

Response: We thank the commenters for their suggestions and will take them into consideration as we consider options for updating the complex patient bonus in future years. Further, while the ASPE's second report is supportive of the complex patient bonus, they have specific recommendations as to how to further incorporate risk adjustment at the MIPS program level which we plan to address in future rulemaking. Additionally, although the ASPE report found dual eligibility to be a reliable indicator of social risk, we understand there may be some limitations. However, we are not aware of data sources and/or methodologies to account for other social indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient's complexity. Further, we continue to believe that average HCC risk scores are a valid proxy for medical complexity that are also used by other CMS programs. Therefore, we have decided to continue to pair the HCC risk score with the proportion of dually eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We will evaluate additional, more comprehensive options, such as the utilization of ICD–10 Z codes, in future years based on any updated data or additional information, including to better account for social risk factors while minimizing unintended consequences and consider these as we move forward.

Comment: One commenter expressed concerns with calculating the complex patient bonus points given the substantial disruptions to patient care due to the national PHE for COVID–19, which could cause data, used for the lookback period, to be either compromised or unreliable.

Response: When we calculate the complex patient bonus points, we rely on dual eligibility status and the HCC risk score, which should not be impacted by potential coding modifications or disruptions for the CY 2020 performance period. Pursuant to § 414.1380(c)(3)(i), in order to calculate an average HCC risk score, CMS uses the model adopted under section 1853 of the Act for Medicare Advantage risk adjustment purposes, for each MIPS eligible clinician or group; that average HCC risk score is used as a part of the complex patient bonus calculation. We refer readers to the CY 2018 QPP final rule (82 FR 53771) for more details on how we calculate the average HCC risk score for a MIPS eligible clinician or group. Specifically, we average HCC risk scores for beneficiaries cared for by the MIPS eligible clinician or clinicians in the group during the second 12-month segment of the eligibility period during the prior performance period. HCC risk scores for beneficiaries would be calculated based on the calendar year immediately prior to the performance period. For example, for the 2020 MIPS performance period, the HCC risk scores would be calculated based on beneficiary services from CY 2019, which is prior to the year in which the PHE occurred. Additionally, as the claims coding for the HCC occurred prior to this proposal, we believe this approach mitigates the risk of potential coding modifications or disruptions to get higher expected costs, which could happen if concurrent risk adjustments were incorporated. However, we acknowledge some of the policy flexibilities we established for the national PHE for COVID–19 potentially could have an effect on data for CY 2020. Given that this is the primary source of data available to us to calculate the complex patient bonus for CY 2021, for now, we plan to utilize this data, and we will monitor and consider making additional adjustments, as necessary.

After consideration of the public comments, we are finalizing the proposal to continue the complex patient bonus for the 2021 performance period/2023 MIPS payment year as proposed and to revise § 414.1380(c)(3) accordingly.

(iii) Complex Patient Bonus for the 2022 MIPS Payment Year

In this section of the final rule, we discuss the proposed policy to modify the complex patient bonus for the 2022 MIPS payment year in response to the PHE for COVID–19 (85 FR 50311). In the CY 2020 PFS final rule, we continued the complex patient bonus for the 2020 performance period/2022 MIPS payment year (84 FR 63021 through 63023). More specifically, we continued to utilize our two established complexity indicators, HCC risk scores and dual eligible status, because we believed that they continued to account for the multitude of factors that describe and have an impact on patient health outcomes. Further, risk scores are based on a beneficiary's age and sex; whether the beneficiary is eligible for Medicaid, first qualified for Medicare on the basis of disability, or lives in an institution (usually a nursing home); and the beneficiary's diagnoses from the previous year.[127] Additionally, the HCC model also accounts for the number of conditions a beneficiary has, making an adjustment as the number of diseases or conditions increases, and includes additional diagnosis codes related to mental health and substance use disorders, and chronic kidney disease.[128] However, due to the national PHE for COVID–19 during performance period 2020, we noted that we need to re-evaluate the previously established policy for the complex patient bonus for the 2022 MIPS payment year. We acknowledged that there are direct effects of COVID–19 for those patients who have the disease and indirect effects of COVID–19 for other patients, including increased complexity and barriers such as postponing care, accessing care in a different way (for example, via telecommunications), and disruptions to lab results and medications, which are not accounted for in our existing final score calculations using these complexity indicators. We noted that we realize that the first year of the novel virus may add complexity that we have not already captured via the complex patient bonus. This complexity includes patients who have gotten sick, as well as patients who may now have complications or other factors because of delayed care or disruptions to lab services or medications due to COVID–19. Government guidelines, such as the Centers for Disease Control and Prevention (CDC) guidance on ''Groups

[127] CMS, Medicare Fee-For-Service Provider Utilization & Payment Data Physician and Other Supplier Public Use File: A Methodological Overview'': *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare-Physician-and-Other-Supplier-PUF-Methodology.pdf.*

[128] CMS, ''Report to Congress: Risk Adjustment in Medicare Advantage'': *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.*

at Higher Risk for Severe Illness'', indicate that COVID–19 patients who are already high-risk due to pre-existing medical conditions are at further risks of increased COVID–19 related hospitalizations and mortality.[129] Further, literature also indicates that those patients who are already high-risk due to social factors are also at further risk of serious illness related to COVID–19.[130]

Further, during this time, hospitals reported that medical systems delayed and canceled care, resulting in reduced utilization of healthcare services and a changing care delivery system.[131] Although access to Medicare telehealth services was expanded so that beneficiaries could receive a wider range of services from clinicians without having to travel to a healthcare facility,[132] this only partially filled the gap in services from the reduction in delivery of care, as not all specialties can utilize telehealth. We recognized the increased challenges of providing care to complex patients in the context of the national PHE for COVID–19. Patients with comorbidities (as measured by HCC risk score) and social risk (measured by dual eligible status) are disproportionately likely to be severely affected by COVID–19.[133] [134] [135] More specifically, findings from our recently released data reinforces previous findings by the CDC that older Americans and those with chronic health conditions are at the highest risk for COVID–19. The data also show that COVID–19 has disproportionately impacted lower income adults, further confirming longstanding healthcare disparities in dually eligible populations.[136] Additionally, in light of the care delivery changes, we noted that clinicians may see patients in 2020, with medical or social risk factors, whose health conditions may have been exacerbated due to delayed care. Patients with comorbidities and social risk are likely to suffer adverse outcomes due to delaying or not receiving care.[137] [138] [139] Given that the limited available literature and data on COVID–19 suggests that patients with social risk factors or underlying conditions have increased complexity, we believe that our existing complexity indicators, HCC risk score and dual eligibility, could serve as a proxy for capturing increased complexity due to the PHE for COVID–19.

Currently, the complex patient bonus is worth up to 5 points. However, given the anticipated increase in complexity due to the national PHE for COVID–19, we proposed at § 414.1380(c)(3)(iv) that for the CY 2020 performance period/2022 MIPS payment year, the complex patient bonus would be calculated pursuant to the existing formulas in § 414.1380(c)(3)(i) and (ii), and the resulting numerical value would then be multiplied by 2, but the complex patient bonus cannot exceed 10. The doubled numerical value (subject to the 10-point cap) would be added to the final score. Additionally, we proposed to revise § 414.1380(c)(3)(iii) to state that the complex patient bonus cannot exceed 5.0 except as provided in § 414.1380(c)(3)(iv). As proposed, clinicians could receive up to 10 complex patient bonus points added to their final score. For example, if a MIPS eligible clinician were to receive 4 complex patient bonus points under the existing formulas, the MIPS eligible clinician would receive 8 complex patient bonus points (doubling the bonus points) under our proposal for the CY 2020 performance period/2022 MIPS payment year. In instances where clinicians would have received the maximum of 5 complex patient bonus points, they would receive the maximum of 10 complex patient bonus points under our proposal for the CY 2020 performance period/2022 MIPS payment year. To the extent that the proposed change constitutes a change to the MIPS scoring or payment methodology for the 2022 MIPS payment adjustment after the start of the 2020 performance period, we noted that we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to account for increased patient complexity due to the national PHE for COVID–19. We believe it would be contrary to the public interest if MIPS scores do not adequately recognize this increased patient complexity that could not have been accounted for during the CY 2020 rulemaking. More specifically, as discussed in the CY 2021 PFS proposed rule, we are unable to measure the magnitude of the direct and indirect effects of the PHE for COVID–19 on MIPS scores, and we remain concerned about potentially misidentifying poor performance with regard to the care delivered in CY 2020 due to the PHE for COVID–19 (85 FR 50312). Hence, we believe this approach of doubling the complex patient bonus recognizes the difficulty of managing complex patients during the PHE for COVID–19 and lowers the risk of inaccurately identifying a clinician as a ''poor performer'' when the underlying issue is caring for increasingly complex patients due to both direct and indirect effects of COVID–19.

Due to limited data available related to the PHE for COVID–19, we noted that it is difficult to gauge whether the proposal would be artificially increasing MIPS final scores or not providing enough flexibility to clinicians to account for increased patient complexity during the CY 2020 performance period. Given the challenges we assumed clinicians may be facing, we noted that doubling the complex patient bonus would be a reasonable and operationally feasible approach. In developing our proposal, we considered several alternatives, including maintaining the complex patient bonus as it currently is (up to 5 points), as well as whether it would be appropriate to triple (up to 15 points) the complex patient bonus. However, due to the limited data available, we did not propose those options as we were concerned that an approach of tripling

[129] CDC, ''Groups at Higher Risk for Severe Illness'': *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html*.

[130] Kaiser Family Foundation, ''Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus'': *https://www.kff.org/coronavirus-covid-19/issue-brief/low-income-and-communities-of-color-at-higher-risk-of-serious-illness-if-infected-with-coronavirus/*.

[131] American Hospital Association, ''Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID–19'': *https://www.aha.org/guidesreports/2020–05–05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due*.

[132] CMS, ''Medicare Telemedicine Healthcare Provider Fact Sheet'': *https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet*.

[133] The Journal of the American Medical Association Network, ''Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized with COVID–19 in the New York City Area'': *https://jamanetwork.com/journals/jama/fullarticle/2765184*.

[134] Morbidity and Mortality Weekly Report/CDC COVID–19 Response Team, ''Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019—United States, February 12–March 28, 2020'': *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7119513/pdf/mm6913e2.pdf*.

[135] The Commonwealth Fund, ''Assessing Underlying State Conditions and Ramp-Up Challenges for the COVID–19 Response'': *https://www.commonwealthfund.org/publications/issue-briefs/2020/mar/assessing-underlying-state-conditions-and-ramp-challenges-covid*.

[136] CMS, ''Medicare COVID–19'' Data Release Blog'': *https://www.cms.gov/blog/medicare-covid-19-data-release-blog*.

[137] Kaiser Health News, ''Nearly Half of American Delayed Medical Care Due to Pandemic'': *https://khn.org/news/nearly-half-of-americans-delayed-medical-care-due-to-pandemic/*.

[138] The British Medical Journal, ''Delayed presentation of acute ischemic strokes during the COVID–19 crisis'': *https://jnis.bmj.com/content/early/2020/05/27/neurintsurg-2020-016299*.

[139] US National Library of Medicine National Institutes of Health, ''Hospitalization for Ambulatory-care-sensitive Conditions in Taiwan Following the SARS Outbreak: A Population-based Interrupted Time Series Study'': *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135451/*.

the bonus could artificially increase final scores and maintaining the current bonus (up to 5 points) may not be sufficient to account for the increased patient complexity during the CY 2020 performance period. Additionally, we noted that we believe that by doubling the complex patient bonus, clinicians whose MIPS performance may be negatively affected by the challenges of caring for a complex patient population during a PHE will be less likely to have the maximum negative adjustment due to circumstance beyond their control.

We also considered whether we should add a new indicator of patient complexity, such as establishing a threshold for the percentage of patients with COVID–19. We expressed concern about this alternative approach for two reasons. First, we did not believe the effects of COVID–19 are limited to those patients who are experiencing the illness. Second, there was uncertainty of the consistency of diagnosis coding for both patients who are experiencing the illness or who are being treated for the sequelae of the illness.

We requested comments on our proposal, the alternatives we considered, and any other approaches to account for patient complexity during the PHE for COVID–19 that commenters believe we should consider, as well as alternative data sources for patient complexity. We invited public comments on our proposal to double the complex patient bonus for the CY 2020 performance period/2022 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to double the complex patient bonus for the CY 2020 performance period/2022 MIPS payment year. One commenter appreciated CMS' proposal to double the complex patient bonus points but suggested that CMS provide additional flexibility, including further modifying the complex patient bonus policy to create accountability for achieving equity for all Medicare beneficiaries, both within and outside the context of the PHE for COVID–19.

Response: We will continue to assess and expand our understanding of both the direct and indirect impact of the PHE for COVID–19 and will incorporate additional data and findings in future rulemaking. We want to note that in addition to the complex patient bonus proposal, we also announced that clinicians and practices affected by the PHE for COVID–19 could apply for reweighting of the MIPS performance categories due to extreme and uncontrollable circumstances. We refer readers to *https://qpp.cms.gov/about/covid19* for the flexibilities provided during the PHE for COVID–19.

Comment: A few commenters agreed that the complex patient bonus for the CY 2020 performance period should be increased but recommended CMS to consider alternatives. One commenter suggested that CMS consider providing more than 10 complex patient bonus points in areas of the country that are most impacted by COVID–19. For example, the commenter suggested that CMS look at areas that are among the top ranking in positive cases. Another commenter suggested that doubling the complex patient bonus is fair but suggested CMS to consider increasing the complex patient bonus points by more than double. A few commenters encouraged CMS to make this increase permanent and one specifically recommended a permanent increase until more clinically appropriate quality measures are developed. Another commenter suggested that CMS increase the complex patient bonus points for CY 2020 to 15 points and then 10 points for CY 2021 to recognize the ongoing effects of the national PHE.

Response: We thank the commenters for their support and their suggestions to further revise the complex patient bonus policy. With regard to assessing which areas of the country are more impacted by COVID–19, we believe it is difficult to assess the true impact in certain areas. More specifically, it could be possible that the impacted areas may change throughout the year, making it difficult to assess which areas are treating more complex patients. For example, back in spring of 2020, New York faced an initial surge of COVID–19 cases.[140] However, overtime, data is indicating that certain areas in the Midwest region are now seeing an influx of COVID–19 cases as cases in New York are decreasing.[141] Furthermore, we have identified the PHE for COVID–19 as a national event, and therefore, we believe it is appropriate to apply one policy for the national event as opposed to establishing different policies for varying geographic areas. However, we will continue to assess the impact of the PHE and consider whether to further modify the policy in future rulemaking. Additionally, as indicated in the comment summary above, a few commenters suggested that we consider further increasing the complex patient bonus points beyond 10 points. As noted in the CY 2021 PFS proposed rule (85 FR 50312), we considered several alternatives, including maintaining the complex patient bonus as it currently is (up to 5 points), as well as whether it would be appropriate to triple (up to 15 points) the complex patient bonus. However, due to the limited data available, we decided not to propose those options because we were concerned that tripling the bonus could artificially increase final scores and maintaining the current bonus (up to 5 points) may be insufficient to account for the increased patient complexity during the CY 2020 performance period. We acknowledge that the impact of the national PHE for COVID–19 may affect CY 2021 and intend to continue to offer the application-based extreme and uncontrollable circumstances policy for CY 2021, as referenced in section IV.A.3.d.(2)(b)(iv)(B) of this final rule, while we continue to assess the impact and our established related policies. Hence, we continue to believe this one-time adjustment of doubling the complex patient bonus is important and believe that an increase of up to 10 points is appropriate.

Comment: A few commenters stated concerns with doubling the complex patient bonus points for the CY 2020 performance period/CY 2022 MIPS payment year. One commenter stated that offering up to 10 complex patient bonus points could potentially mask poor performance and reward clinicians who did not treat significant numbers of complex COVID–19 patients. The commenter also stated concerns with clinicians potentially upcoding due to this policy change. Another commenter stated concerns with potentially diluting the overall MIPS score for groups and potentially skewing the national average. Another commenter said it would be inappropriate to have complex patient bonus points tied to the number of COVID–19 cases a particular clinician sees.

Response: We thank the commenters for their responses. We acknowledge that doubling the complex patient bonus could potentially mask poor performance or skew the national average, but we are weighing these potential effects against the unforeseen complexity of caring for complex patients during the national PHE for COVID–19. We disagree that doubling the complex patient bonus would dilute the overall score. As discussed above, we considered a complex patient bonus of up to 15 points but believe that a bonus of up to 10 appropriately

[140] John Hopkins University & Medicine, ''Coronavirus Resource Center'' *https://coronavirus.jhu.edu/data/state-timeline/new-confirmed-cases/new-york.*

[141] Modern Healthcare, ''Hospitals feel squeeze as coronavirus spikes in Midwest'': *https://www.modernhealthcare.com/hospitals/hospitals-feel-squeeze-coronavirus-spikes-midwest.*

balances our desire to account for the PHE without artificially increasing scores. Additionally, we rely on dual eligibility status and the HCC risk score, in order to calculate the complex patient bonus for the performance period. We believe this methodology would continue to appropriately account for the increased complexity we are seeing in light of the PHE while balancing the impact of caring for patients with both medical and social risks. We also acknowledge that doubling the complex patient bonus could potentially reward clinicians who did not treat significant number of complex COVID–19 patients. We intend to provide this one-time adjustment of doubling the complex patient bonus because we recognize that there are both direct and indirect effects of the national PHE for COVID–19. For example, clinicians who have not cared for COVID–19 patients are, nevertheless, dealing with the indirect impact of delayed care for complex patients. Alternatively, for clinicians who have cared for COVID–19 patients, we believe this adjustment would account for the medical complexity the clinician directly faces in treating these patients. Hence, we continue to believe that an adjustment of up to 10 points is appropriate to account for both direct and indirect potential impacts on clinicians and care delivery due to the PHE. Finally, we disagree that this policy proposal could encourage upcoding. As we explained in a previous response to comments, when we calculate the complex patient bonus points, we rely on dual eligibility status and the HCC risk score, which should not be impacted by potential coding modifications or disruptions for the CY 2020 performance period. The HCC risk score for CY 2020 is calculated based on data from CY 2019, the year prior to the national PHE for COVID–19.

Finally, the proposed policy would be calculated pursuant to the existing formulas in § 414.1380(c)(3)(i) and (ii), and we do not intend to alter the formula based on the number of COVID–19 cases a clinician sees. As we noted in the CY 2021 PFS proposed rule (85 FR 50313), we considered whether we should add a new indicator of patient complexity, such as establishing a threshold for the percentage of patients with COVID–19, and we continue to be concerned about this alternative approach for two reasons including: (1) The effects of COVID–19 are not limited to those patients who are experiencing the illness; and (2) we are still uncertain of the consistency of diagnosis coding for both patients who are experiencing the illness or who are being treated for the sequelae of the illness.

Comment: One commenter stated concerns with doubling the complex patient bonus points given that the additional resources utilized to treat COVID–19 patients are already being accounted for through Part A and Part B reimbursement, such as lab tests and medically necessary hospitalizations, and should not be additionally funded by the Quality Payment Program.

Response: We disagree that doubling the complex patient bonus points would be redundant of Part A and Part B reimbursement. The purpose of the complex patient bonus is to account for risk factors through appropriate adjustments to MIPS scoring. The policy is not intended to reimburse clinicians for costs associated with treating more complex patients.

After consideration of the public comments, we are finalizing our proposal for the complex patient bonus for the CY 2020 performance period/ 2022 MIPS payment year as proposed. We are finalizing § 414.1380(c)(3)(iv), under which the complex patient bonus will be calculated pursuant to the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value will then be multiplied by 2, but cannot exceed 10.0. The doubled numerical value (subject to the 10-point cap) will be added to the final score. Additionally, we finalize our proposal to revise paragraph (c)(3)(iii) to state that the complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv).

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2020 PFS final rules (81 FR 77320 through 77329, 82 FR 53779 through 53785, 83 FR 59870 through 59878, and 84 FR 62950 through 84 FR 62959, respectively). In section IV.A.3.c.(2)(a) of the CY 2021 PFS proposed rule, we proposed that the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. In section IV.A.3.c.(1) of that proposed rule, we proposed the quality performance category would thus make up 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. In sections III.K.3.c.(1)(b) and III.K.3.c.(2)(a) of this final rule, we finalized these proposed weights for the quality and cost performance categories for the 2023, 2024, and subsequent MIPS payment years as proposed. Table 50 summarizes the weights for each performance category.

TABLE 50: Weights by MIPS Performance Category for the 2023, 2024, and Future MIPS Payment Years

Performance Category	2023 MIPS Payment Year	2024 and Future MIPS Payment Years
Quality	40%	30%
Cost	20%	30%
Improvement Activities	15%	15%
Promoting Interoperability	25%	25%

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician generally would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Under certain circumstances, however, a MIPS eligible clinician who fails to report could be eligible for an assigned scoring weight of zero percent and a redistribution of the performance category weights. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2020 PFS final rule (84 FR 63023 through 63027).

(iii) Redistributing Performance Category Weights

In the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2020 PFS final rules (81 FR 77325 through 77329, 82 FR 53783 through 53785, 83 FR 59876 through 59878, and 84 FR 63027 through 63031), and at § 414.1380(c)(2)(ii), we established policies for redistributing the weights of performance categories in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories. Under these policies, we generally redistribute the weight of a performance category or categories to the quality performance category because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. For the 2020 MIPS performance period and 2022 MIPS payment year, we did not redistribute performance category weights to improvement activities, except for the scenario where the only two performance categories being scored are improvement activities and cost (84 FR 63028). Also for that year in scenarios when the cost performance category weight is redistributed while the Promoting Interoperability performance category weight is not, we redistributed a portion of the cost performance category weight to the Promoting Interoperability performance category, as well as to the quality performance category (84 FR 63027). As stated in CY 2020 PFS final rule, we continue to believe this redistribution policy is appropriate given our focus on working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act (the Cures Act) (Pub. L. 114–255, enacted on December 13, 2016) to ensure seamless but secure exchange of health information for clinicians and patients and emphasize the importance of interoperability without overwhelming the contribution of the quality performance category to the final score (84 FR 63027).

In the CY 2021 PFS proposed rule (85 FR 50293), we proposed a weight for the cost performance category of 20 percent for the 2023 MIPS payment year. For the 2023 MIPS payment year, we proposed similar redistribution policies as finalized for the 2022 MIPS payment year, with minor modifications to account for the cost performance category being 20 percent. As proposed, we would once again only redistribute weight to the cost performance category in cases when the cost and improvement activities performance categories are the only categories scored (each of these performance categories would be 50 percent in this scenario). We noted that we do not believe it is appropriate to redistribute more weight to the cost performance category, because cost would not yet be at the maximum weight specified by the statute (30 percent), and because clinicians still have relatively limited experience being scored on and receiving feedback on cost measures compared with quality measures. Our proposed redistribution policies for the 2023 MIPS payment year, which we proposed to codify at § 414.1380(c)(2)(ii)(E), are included in Table 45 of CY 2021 PFS proposed rule (85 FR 50314).

In the CY 2021 PFS proposed rule (85 FR 50294), we proposed to weight the cost performance category at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year, as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. Given that 2024 would be the first year that cost would be set at the maximum weight prescribed by the statute, we noted that we did not believe it would be prudent to begin redistributing more weight to cost for the 2024 MIPS payment year, except in cases when only the cost and improvement activities performance categories are scored. For the improvement activities performance category, we are only assessing whether a MIPS eligible clinician completed certain activities (83 FR 59876 through 59878). Because MIPS eligible clinicians will have had several years of experience reporting under MIPS, we noted that it is important to prioritize performance on measures that show a variation in performance, rather than the activities under the improvement activities performance category, which are based on attestation of completion. We also noted that we believe this helps to reduce incentives to not report measures for the quality performance category in circumstances when a clinician may be able to report but chooses not to do so. For example, when a clinician may be able to report on quality measures, but chooses not to report because they are located in an area affected by extreme and uncontrollable circumstances as identified by CMS and qualify for reweighting under § 414.1380(c)(2)(i)(A)(8). Therefore, we noted that we continue to believe that weighting the cost and improvement activities performance categories each at 50 percent would be an appropriate balance (84 FR 63027). As for the other reweighting scenarios, we plan to revisit our redistribution policies in future rulemaking and may consider redistributing more weight to the cost performance category after clinicians have more experience with cost being weighted at 30 percent. Our proposed redistribution policies for the 2024 MIPS payment year, which we proposed to codify at § 414.1380(c)(2)(ii)(F), are included in Table 46 of CY 2021 PFS proposed rule (85 FR 50315).

We invited public comments on our proposed redistribution policies for the 2023 and 2024 MIPS payment years. The following is a summary of the comments we received and our responses.

Comment: A few commenters were supportive of CMS' proposal to redistribute the category weights. One commenter specifically agreed with CMS' reweighting proposals in instances when only the quality performance category and the improvement activities performance category are scored. A few commenters specifically supported CMS' proposal to not redistribute weight to the cost

performance category except in cases when only cost and improvement activities performance categories are scored. One commenter stated that the reweighting polices builds confidence in the program and demonstrates transparency.

Response: We thank the commenters for their support. We agree that our reweighting policies allow for flexibility, leading to confidence and transparency within the program. We also appreciate commenters' support in our policy rationale for not redistributing weight to the cost performance category except in cases when only cost and improvement performance categories are scored.

Comment: One commenter requested that CMS should not redistribute weights to the cost performance category until that performance category has more relevant and applicable cost measures available across all specialties.

Response: We agree with the commenter that there is currently a limited set of cost measures within the cost performance category. However, we do have concerns with redistributing a substantial portion of the performance category weights to the improvement activities performance category for several reasons. Specifically, through our redistribution policies, we aim to prioritize interoperability, performance on measures that show a variation in performance, and performance categories that have some or all measures that focus on performance, as compared to the activities under the improvement activities performance category, which are solely based on attestation of completion. We continue to believe that we should not redistribute weight to the improvement activities performance category. We also note that, given that 2024 would be the first year that cost would be set at the maximum weight prescribed by the statute, we continue to believe it would not be prudent to begin redistributing more weight to cost for the 2024 MIPS payment year, except in cases when only the cost and improvement activities performance categories are scored. We should give clinicians more time to adjust to new and revised cost measures before redistributing more weight to the cost performance category. However, similar to all performance categories of MIPS, there are continued opportunities to improve the measures and activities used to assess performance. We also continue to provide detailed performance feedback on the cost measures to clinicians and expect to provide detailed feedback on any new and revised cost measures in the future, providing clinicians a further opportunity to improve their performance within cost measures. Hence, we continue to believe that reweighting the cost and improvement activities performance categories each at 50 percent would appropriately continue to balance our concerns with redistributing weight to the improvement activities performance category.

Comment: One commenter requested that if CMS finalizes the proposal to increase the cost performance category weight, then CMS take the Promoting Interoperability and improvement activities performance category weights and further redistribute them within the cost performance category due to a concern that these two performance categories do not reward the actual results on improvement in quality of care.

Response: As is reflected in our proposals, we do not intend to redistribute a substantial portion of the performance category weight to the improvement activities performance category given that we intend to prioritize performance on measures that show a variation in performance, rather than the activities under the improvement activities performance category, which are based on attestation of completion. However, we believe that both the Promoting Interoperability and improvement activities performance categories reflect important aspects of quality improvement performance. More specifically, over time, we want to redistribute more weight to the cost and Promoting Interoperability performance categories, and less to the quality performance category, to have better alignment between the cost and quality performance categories and due to our focus on interoperability. We also disagree that we should redistribute more weight within the cost performance category than we have proposed, as clinicians are still adjusting to newly developed cost measures. As noted in our previous response, we do not believe that the cost performance category weight should be minimized but should also remain at the proposed 50 percent weight in instances of where only the cost and improvement activities performance categories are scored.

After consideration of the public comments, we are finalizing our proposed redistribution policies for the 2023 and 2024 MIPS payment years as proposed, and the codification of those policies at § 414.1380(c)(2)(ii)(E) and (F). Our finalized redistribution policies for both the 2023 and 2024 MIPS payment years are included in Table 51 and 52.

TABLE 51: Performance Category Redistribution Policies Finalized for the 2023 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	40%	20%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	65%	20%	15%	0%
-No Quality	0%	20%	15%	65%
-No Improvement Activities	55%	20%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	80%	20%	0%	0%
-No Quality and no Improvement Activities	0%	20%	0%	80%

TABLE 52: Performance Category Redistribution Policies Finalized for the 2024 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	55%	30%	15%	0%
-No Quality	0%	30%	15%	55%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

(iv) MIPS Applications for Reweighting for the 2021 and 2023 MIPS Payment Years Based on Extreme and Uncontrollable Circumstances

(A) MIPS Applications for Reweighting for the 2021 MIPS Payment Year Based on Extreme and Uncontrollable Circumstances

Recognizing the urgency of the PHE for COVID–19, we published the March 31st COVID–19 IFC modifying Medicare rules, including the PFS, so that physicians and other practitioners and clinicians are allowed added flexibilities due to the PHE for COVID–19. To provide relief to individual clinicians, groups, and virtual groups for whom sufficient MIPS measures and activities may not be available for the 2019 MIPS performance period due to the PHE for the COVID–19, we extended the deadline to submit an application for reweighting the quality, cost, and improvement activities performance categories (§ 414.1380(c)(2)(i)(A)(*6*)), as well as the Promoting Interoperability performance category (§ 414.1380(c)(2)(i)(C)(*2*)) based on extreme and uncontrollable circumstances from December 31, 2019 to April 30, 2020, or a later date that we may specify (85 FR 19278). The extended deadline is available only for applications that demonstrate the clinician has been adversely affected by the PHE for the COVID–19. We also modified the policy at § 414.1380(c)(2)(i)(A)(*6*) to create an exception for the 2019 performance period/2021 MIPS payment year only, such that if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the PHE for the COVID–19, but also submits data for the quality, cost, or improvement activities performance categories, the performance categories for which data are submitted would still be reweighted (subject to CMS' approval of the application), and the data submission would not effectively void the application for reweighting (85 FR 19278). We also modified the policy at

§ 414.1380(c)(2)(i)(C) to create a similar exception for the Promoting Interoperability performance category for the 2019 performance period/2021 MIPS payment year only (85 FR 19278).

We invited public comments on these interim final policies. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for CMS' efforts to reduce administrative burden for physicians through increased availability of the extreme and uncontrollable circumstances policies. Commenters expressed their belief that these changes are necessary because it may be difficult for clinicians to meet data submission requirements for the Quality Payment Program due to circumstances beyond their control.

Response: We thank commenters for their support of our policies.

Comment: A few commenters requested that we modify our extreme and uncontrollable circumstances policies so that if clinicians do not submit an application for extreme and uncontrollable circumstances and submit data and achieve a score above the performance threshold, we use that score for payment purposes. However, in cases where clinicians achieve a score below the performance threshold, we will not use that score for payment purposes.

Response: We do not believe the approach requested by the commenters would be consistent with the statute. We do not believe the statute gives us discretion to disregard scores below the performance threshold and only apply the MIPS payment adjustments based on scores above the performance threshold.

Comment: One commenter stated that we should not require clinicians to demonstrate that they are impacted by the PHE for COVID–19 in order to receive reweighting under our extreme and uncontrollable circumstances policies.

Response: We note that we assume most clinicians are impacted by the PHE for COVID–19. However, we recognize that not all clinicians and practices have been impacted to the same extent, and therefore, may not all need reweighting. We requested that clinicians select COVID–19 as the reason for requesting reweighting and provide a brief narrative describing how they have been impacted. More information is available at *https://qpp.cms.gov/about/covid19?py=2020*.

Comment: One commenter expressed the belief that we should provide reweighting automatically under our extreme and uncontrollable circumstances policies unless clinicians opt in for participation in the Quality Payment Program.

Response: We believe that requiring clinicians to opt in to be scored within the Quality Payment Program would place undue burden on clinicians who submitted information intending to participate in the program.

After consideration of the public comments, we are adopting these interim final policies as final without any modifications. We are finalizing the regulation text at § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C).

(B) MIPS Applications for Reweighting for the 2023 MIPS Payment Year Based on Extreme and Uncontrollable Circumstances

We anticipate that the national PHE for COVID–19 will continue into and through CY2021. Therefore, we remind clinicians that the application-based extreme and uncontrollable circumstances policy, as described in § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*), will be available for the 2021 performance period/2023 MIPS payment year (please refer to *https://qpp.cms.gov/about/covid19?py=2020* for details). The application allows clinicians, groups, and virtual groups significantly impacted by the PHE for COVID–19 to request reweighting for any or all MIPS performance categories. Under this policy, however, if a clinician, group, or virtual group decides to submit data for the 2021 performance period, the data submission will override the application, and the clinician, group, or virtual group will be scored on the data submitted. We believe this approach maintains a balance of encouraging participation in the Quality Payment Program while still providing for flexibility in weighting the performance categories for those who have been affected by the COVID–19 pandemic. Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for more information.

e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score hierarchy used to determine MIPS payment adjustments, we refer readers to the CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799) and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343). In the CY 2021 PFS proposed rule (85 FR 50315 through 50321), we proposed to modify these policies: (1) To reflect the discontinuation of the APM scoring standard and the addition of the APM Performance Pathway (APP), both as proposed in the CY 2021 PFS proposed rule (85 FR 50303); (2) to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized; and (3) to potentially revisit and revise the prior estimate of the performance threshold for the 2024 MIPS payment year.

(2) Final Score Hierarchy Used in Payment Adjustment Calculation

In some cases, a TIN/NPI could have more than one final score associated with it from a performance period, if the MIPS eligible clinician submitted multiple data sets. In the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we established the following final score hierarchy that applies as displayed in Table 53 when more than one final score is associated with a TIN/NPI.

TABLE 53: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Example	Final Score Used to Determine Payment Adjustments
TIN/NPI has more than one APM Entity final score.	The highest of the APM Entity final scores.
TIN/NPI has an APM Entity final score and also has an individual score.	APM Entity final score.
TIN/NPI has an APM Entity final score that is not a virtual group score and also has a group final score.	APM Entity final score.
TIN/NPI has an APM Entity final score and also has a virtual group score.	APM Entity final score.
TIN/NPI has a virtual group score and an individual final score.	Virtual group score.
TIN/NPI has a group final score and an individual final score, but no APM Entity final score and is not in a virtual group.	The highest of the group or individual final score.

With the proposed discontinuation of the APM scoring standard and addition of the APP in section IV.A.2.b.(5) of the CY 2021 PFS proposed rule, we proposed to modify the existing final score hierarchy beginning with the 2021 performance period/2023 MIPS payment year. In the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we finalized prioritizing the APM Entity final score over any other score for a TIN/NPI by using the waiver authority for Innovation Center models under section 1115A(d)(1) of the Act and the Shared Savings Program waiver authority under section 1899(f) of the Act to waive section 1848(q)(5)(I)(i)(I) and (II) of the Act so that we could use the APM Entity final score instead of the virtual group final score for a TIN/NPI. This hierarchy was intended to incentivize APM participation; however, we proposed to terminate the APM scoring standard in section IV.A.2.b.(5) of the CY 2021 PFS proposed rule, and while we believe it is important to still encourage movement to APMs, we stated that we do not believe that prioritizing an APM Entity score over other reported MIPS data would necessarily further our goal of increasing APM participation. The proposed modifications to the final score hierarchy would include MIPS eligible clinicians who are reporting through the APP, which is designed to provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation. MIPS eligible clinicians who are already participating in APMs, and therefore, have different reporting obligations than MIPS eligible clinicians, who have not already taken that step, can opt to report through the APP and receive an APP final score that may be used in the MIPS payment adjustment calculation. Beginning with the 2021 performance period/2023 MIPS payment year, if a TIN/NPI has a virtual group final score associated with it, we proposed to use the virtual group final score to determine the MIPS payment adjustment. If a TIN/NPI does not have a virtual group final score associated with it, we proposed to use the highest available final score associated with the TIN/NPI to determine the MIPS payment adjustment. We stated that the proposal was consistent with section 1848(q)(5)(I)(i) of the Act, which requires us to prioritize a virtual group final score over other final scores such as individual and group scores (82 FR 53786). We stated that we believe that using the highest final score available regardless of how the clinician chose to submit data to MIPS would benefit all MIPS eligible clinicians. For example, we have noticed some instances where prioritizing the APM Entity final score over other final scores has resulted in some clinicians not receiving the highest final score associated with their TIN/NPI, which may have the unintended consequence of moving clinicians away from APM participation. As we seek to move more clinicians into APMs, we believe using their highest score regardless of participation method would benefit all MIPS eligible clinicians. With the establishment of MVPs, we intend to revisit policies regarding the final score hierarchy used for payment adjustment determinations in future rulemaking.

Table 54 illustrates the proposed modified final score hierarchy.

TABLE 54: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, an APP final score, a group final score, and/or an individual final score.	Virtual group final score.
TIN/NPI has an APM Entity final score, an APP final score, a group final score, and/or an individual final score, but is not in a virtual group.	The highest of the available final scores.

The following is a summary of the comments we received on the proposal regarding the final score hierarchy used in payment adjustment calculation.

Comment: A few commenters did not support CMS's proposal to modify the scoring hierarchy because of their belief that it may de-emphasize the role of ACOs and may create additional complexity and confusion, urging CMS to minimize the year-to-year changes to scoring policies. One commenter believed that the previous scoring hierarchy, where ACO entities scores took precedent over all other scores, worked well for ACOs and also urged CMS to not make year-to-year changes.

Response: We disagree that the modified scoring hierarchy would de-emphasize the role of ACOs, as we believe it is still important to encourage movement to APMs as we have demonstrated through our policies for the APP and MVPs. As described further in section II.E.1. of this final rule, ACOs participating in the Medicare Shared Savings Program would be required to report through the APP for purposes of determining shared savings under that program; but MIPS eligible clinicians participating in these ACOs also would have the option of reporting outside the APP for purposes of being scored under MIPS, like all other MIPS APM participants, if they should choose to do so. As the APP is optional for purposes of MIPS scoring, MIPS APM participants may report through the APP or through any other available MIPS reporting mechanism they choose. We do not intend to create additional confusion or complexity with our annual policy modifications, but rather provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation.

Comment: A few commenters supported CMS's proposal to modify the final score hierarchy because of their belief that the final score hierarchy allows for flexibility that rewards high performing clinicians, encourages clinicians to continue to participate in the program, simplifies the MIPS final score determination, and benefits all MIPS eligible clinicians. One commenter stated that the modified final score hierarchy may also prevent MIPS APM participants from getting a lower payment adjustment that is based on their APM Entity final score.

Response: We agree that the modified final score hierarchy incentivizes MIPS program participation, simplifies final score determinations and provides beneficial flexibilities for all MIPS eligible clinicians. Although it is not our intent to shield clinicians from payment consequences through our policy changes, it is our intent to encourage continued participation in MIPS, to include APM participants, as well as to provide pathways for participating clinicians to be successful in the program.

Comment: Commenters supported the proposal to modify the existing final score hierarchy and understand that there is a statutory requirement to prioritize the virtual group score, if applicable. The commenters appreciate, that otherwise, CMS would allow use of the best score attributable through individual, group, or APM entity scoring.

Response: We agree that using the highest final score available, regardless of how a MIPS eligible clinician submits data to CMS, would benefit all MIPS eligible clinicians.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to modify the existing final score hierarchy beginning with the 2021 performance period/2023 MIPS payment year.

(3) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

In the CY 2020 PFS final rule (84 FR 63031 through 63037) at § 414.1405(b)(7) and (8), we finalized the performance thresholds for the 2022 and 2023 MIPS payment years at 45 and 60 points, respectively, an increase of 15 points each year until the 2024 MIPS payment year, where we estimated the performance threshold would be 74.01 points (based on actual year 1 performance data and estimates for the third and fourth years) as depicted in Table 55. However, we also stated that we may revisit the performance threshold for the 2023 MIPS payment year in future rulemaking, if we receive additional data that changes our estimate of the performance threshold for the 2024 MIPS payment year.

TABLE 55: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	*Estimated 2024 MIPS Payment Year
	Year 1	Year 2	Year 3	Year 4	Year 5	*Year 6
Performance Threshold	3 points	15 points	30 points	45 points	60 points	*74.01 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	15 points	15 points	*14.01 points

* Prior estimate for the 2024 MIPS payment year (84 FR 63031-63037). This is the estimated performance threshold for year 6 based on modeling projections and is not the finalized performance threshold for year 6.

In the CY 2021 PFS proposed rule (85 FR 50317), we stated that we believe that we should reexamine the performance threshold for year 5 (2021 performance period/2023 MIPS payment year) due to the disruptions caused by the PHE for COVID–19. We anticipated some clinicians not having sufficient measures and activities available to participate for the fourth year (2020 performance period/2022 MIPS payment year) and opting to use flexibilities provided for MIPS participation through the extreme and uncontrollable circumstances and hardship exception policies. Furthermore, in considering the effect of the PHE for COVID–19 on clinicians, we stated that we believe that this is enough of a disruption to revisit the performance threshold for year 5, especially for clinicians who are unable to participate in year 4 due to the PHE for COVID–19.

We stated that clinicians who are unable to participate in the fourth year of MIPS due to the PHE for COVID–19, would face an abrupt and large increase in the performance threshold if they return to full participation in the fifth year, lacking the opportunity to work to improve performance. We considered a range of performance threshold values for the fifth year, from 50 to 60 points, and believe that a performance threshold above 50 could be challenging for clinicians affected by the PHE for COVID–19, especially those with small practices. We stated that preliminary analysis has shown that when applying a performance threshold of 50 points to the data we received from the 2021 regulatory impact analysis as summarized in the CY 2021 PFS proposed rule (85 FR 50383), around 31,376 TIN/NPIs (or 5.6 percent of MIPS eligible clinicians) would have payments adjustments that go from negative to positive with a performance threshold of 50 points compared to 60 points. For example, the analysis showed with the previously finalized performance threshold of 60 points, 24.4 percent of engaged small practices would receive a negative payment adjustment, whereas with a performance threshold of 50 points, 18.8 percent of engaged small practices would receive a negative payment adjustment. In analyzing the range of performance threshold values and the impact on high performers as detailed in the CY 2021 PFS proposed rule (85 FR 50383), we saw that in setting the performance threshold at 50 points, the maximum payment adjustment is 6.89 percent whereas when setting the performance threshold at 60 points, the maximum payment adjustment is 7.36 percent, a decrease in percentage by 0.47. To continue to incentivize high performers, we did not revisit the additional performance threshold in the proposed rule, which is set at 85 points for year 5. We proposed to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized at § 414.1405(b)(8). The performance threshold would remain at 30 points in the third year, increase to 45 points in the fourth year, and increase to 50 points in the fifth year. The increase between the third and fifth year would total 20 points. Additionally, and as discussed in more detail below in our discussion of revising the prior estimate of the performance threshold for the 2024 MIPS payment year, we stated that we are open to considering alternatives for the performance threshold for the 2023 MIPS payment year. We solicited comments on the proposed performance threshold of 50 points, the range of values we considered, and any alternatives that commenters believe we should consider for the performance threshold for the 2023 MIPS payment year.

Table 56 depicts the performance threshold for the 2019 MIPS payment year through 2024 MIPS payment year, including the potential change to the performance threshold for the fifth year.

TABLE 56: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	*2022 MIPS Payment Year	**2023 MIPS Payment Year	2024 MIPS Payment Year
	Year 1	Year 2	Year 3	*Year 4	**Year 5	Year 6
Performance Threshold	3 points	15 points	30 points	*45 points *N/A for those who do not participate in year 4	**50 points	74.01 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	*15 points *N/A for those who do not participate in year 4	**5 points for those who participate in year 4 **20 points for those who do not participate in year 4	24.01 points

*Assumed affected payment year due to PHE for COVID-19 resulting in measures not being available for reporting for MIPS participants.

** Proposed new performance threshold for the fifth year.

At the time of publication of the CY 2021 PFS proposed rule, we did not have actual performance scores and other data for year 3 (2019 performance period/2021 MIPS payment year). Since the publication of the CY 2021 PFS proposed rule, we now have the CY 2019 performance year data, where the mean final score is 79.8 and the median final score is 85.27. We note these values are estimates and that the mean and median may change as we finish the targeted review process for the 2021 MIPS payment year. We stated that in the event this information becomes available with sufficient time to inform our policy decisions for the final rule, we proposed to revisit and potentially revise in the final rule our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year. We stated that we anticipated that the actual performance scores for the 2019 performance period/2021 MIPS payment year may be different than the estimates that we published in our regulatory impact analysis estimate (84 FR 63033) because the PHE for COVID–19 occurred during the data submission period. We also expected that the 2019 performance period data may be unusual due to the PHE for COVID–19 occurring during the submission period. We requested comments on our proposal to revisit and potentially revise our prior estimate of the performance threshold for year 6. In particular, we sought comment on what indicators (for example, if the distribution of scores is skewed due to the PHE for COVID–19), if any, should be used to evaluate whether or not the 2019 performance period data are appropriate to use to revise our prior estimate.

Lastly, in the event that we decide to revise our prior estimate of the performance threshold for the 2024 MIPS payment year (either higher or lower) in the final rule, we proposed to consider the revised estimate when we decide on an appropriate numerical value for the performance threshold for the 2023 MIPS payment year. We gave the example that, if we believe that the estimate for the 2024 MIPS payment year performance threshold should be higher than 74.01 (say 80 or 85 points), then we anticipate the performance threshold for the 2023 MIPS payment year would be higher than 50 (likely 55 points, 60 points) to reflect the change in the estimate. We seek to ensure a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year, and thus, we stated that we believe that we should take into account the revised estimate when determining the performance threshold for the 2023 MIPS payment year. We solicited comments on the proposal to consider the revised estimate for the 2024 MIPS payment year when we select a performance threshold for the 2023 MIPS payment year.

The following is a summary of the comments we received on the proposal to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized.

Comment: One commenter did not support lowering the performance threshold to 50 points from the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year, and asked CMS to maintain the performance threshold at 60 points. They referenced the statutory requirement to set the performance threshold to the mean or median of the final scores for a prior period by the CY 2024 MIPS payment year, sharing their concern that lowering the performance threshold for the CY 2023 MIPS payment year may result in a drastic increase when the performance threshold is established for the CY 2024 MIPS payment year. They indicated that this may put undue stress on clinicians who participate in MIPS. A few commenters did not support the change in the performance threshold because MIPS is budget neutral, and thus, decreasing the performance threshold provides little incentive to participate in the program, especially for practices which have made efforts to implement technology, workflows, and improve patient care. One commenter also believed that because of the increase in the complex patient bonus, practices will already be provided relief from the PHE for COVID–19.

Response: We acknowledge the commenter's concern. We agree and believe that maintaining the previously finalized performance threshold of 60 points for the CY 2023 payment year could help to ensure a more consistent increase in the performance threshold from year to year and avoid a potentially

drastic increase between the 2023 and 2024 MIPS payment years. Although we acknowledge that a performance threshold above 50 points could be challenging for clinicians affected by the PHE for COVID–19, we believe it still necessary to incentivize clinicians who are able to participate in MIPS and perform highly despite the PHE. We agree that because the statute includes a budget neutrality requirement for MIPS, decreasing the performance threshold could discourage high performance by decreasing the magnitude of the positive payment adjustments. We want to ensure that there are appropriate incentives for clinicians to continue their participation in MIPS for the 2021 performance period despite the PHE for COVID–19, hence our proposed increase in the complex patient bonus for the 2020 performance period. While we remain concerned with the impact of the PHE for COVID–19 on clinicians, we also want to continue to motivate clinicians to participate in MIPS and strive for high performance on the measures and activities.

Comment: A few commenters supported setting the performance threshold at 50 points for the CY 2021 MIPS performance period/2023 MIPS payment year instead of 60 points as was previously finalized. They believe reducing the performance threshold by 10 points is an appropriate reduction, allows for a small but gradual increase in the performance threshold from year-to-year, and addresses the difficult circumstances practices are facing during the PHE for COVID–19. One commenter also expressed that given uncertainties with the quality benchmarks, they believed a 10-point reduction would be prudent. A few commenters believed that the 10-point reduction in the performance threshold may help small practices in particular, viewing this policy change as consistent with the statute, as well as helping to maintain programmatic stability within MIPS.

Response: We thank the commenters for their recommendations and acknowledge concerns regarding potential challenges for clinicians associated with the PHE for COVID–19. While there are continued uncertainties regarding the impact of the PHE on MIPS eligible clinicians' ability to report for 2020 and 2021 performance period, we cannot ignore that the vast majority of clinicians have been able to successfully report for the 2019 performance period despite the PHE. Data analysis for the 2019 performance period showed fewer requests for reqeighting the MIPS performance categories based on extreme and uncontrollable circumstances than previously expected; however, clinicians impacted by the PHE for COVID–19 may submit an application for reweighting for the 2021 performance period, as discussed in section IV.A.3.d.(2)(b)(iv)(B) of this final rule. We want to ensure that there are appropriate incentives for clinicians, including those with small practices, to continue their participation in MIPS for the 2021 performance period even if the PHE for COVID–19 continues. It is also our intent to prepare clinicians for participation in the MIPS program beyond the PHE for COVID–19 and believe maintaining the performance threshold at 60 points for the 2023 MIPS payment year would align with increasing standards for performance necessary for successfully participating in MIPS in future years.

Comment: One commenter did not support lowering the performance threshold to 50 points from the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year because of their concerns around performance category weights and reweighting policies. They stated the performance threshold for the CY 2023 MIPS payment year should be lowered to 45 points because they believe it would be hard for some clinicians to meet the performance threshold if the cost and Promoting Interoperability performance categories are reweighted to zero percent due to clinician type, as well as a lack of applicable measures.

Response: We acknowledge the commenters concerns and recommendation to set the performance threshold at 45 points for the CY 2023 MIPS payment year. However, we believe that setting the performance threshold at 45 points for the CY 2023 MIPS payment year would create a larger and more abrupt increase in the performance threshold for clinicians who are unable to participate for the 2021 performance period due to the PHE for COVID–19 but choose to participate for the 2022 performance period. Those clinicians would be subject to a minimum of a 29.01 point increase in the performance threshold for the 2022 performance period/2024 MIPS payment year, based on our estimated performance threshold for the 2024 MIPS payment year. Under the policy we are adopting in section XXX of this final rule, if the cost and Promoting Interoperability performance categories are reweighted to zero percent, the quality and improvement activities performance categories will be reweighted to 85% and 15%, respectively. This could provide a scenario that creates greater ease of reaching the performance threshold for clinicians participating in MIPS.

Comment: Several commenters did not support lowering the performance threshold to 50 points from the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year because they believed the performance threshold should be further reduced due to the PHE for COVID–19, limiting regulatory burden for clinicians during that time. Several commenters suggested lowering the performance threshold to 45 points, the same threshold as the CY 2022 MIPS payment year, while one commenter suggested lowering the performance threshold to 30 points, which is the same as the 2021 MIPS payment year. One commenter expressed their belief that further decreasing the performance threshold to 45 points may especially help small and rural practices. Some commenters stated that clinicians who received reweighting of the MIPS performance categories based on extreme and uncontrollable circumstances for the CY 2019 and CY 2020 MIPS performance periods would experience a significant increase in the performance threshold. Another commenter stated that since the final rule may not be published until December 1, 2020, CMS should set the performance threshold to 45 points for the CY 2022 MIPS payment year to provide clinicians with more time to familiarize themselves with the policy changes and decrease the risk of receiving a negative adjustment.

Response: We thank the commenters for their recommendations and acknowledge concerns regarding potential challenges for clinicians due to the PHE for COVID–19. Although small and rural practices may benefit from a lower performance threshold, we believe that it is important to ensure that there are appropriate incentives for clinicians, including small and rural practices, to continue their participation in MIPS for the 2021 performance period and future years, even if the PHE for COVID–19 continues. As discussed in section IV.A.3.d.(2)(b)(iv)(B) of this final rule, the extreme and uncontrollable circumstances application is an available flexibility for clinicians impacted by the PHE for COVID–19. Clinicians who receive reweighting based on extreme and uncontrollable circumstances for the CY 2019, CY 2020, and CY 2021 MIPS performance periods would experience a larger jump in the performance threshold for the CY 2022 MIPS performance period than those who

participated in MIPS for the CY 2019, CY 2020, and CY 2021 MIPS performance periods. However, we believe that maintaining the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year lends consistency to the program, which may be especially important during this challenging time.

The following is a summary of the comments we received on the proposal to revisit and potentially revise in the final rule our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year.

Comment: One commenter expressed their appreciation and belief that CMS has worked to create a smooth transition in increasing the performance threshold in accordance with the statute for the CY 2024 MIPS payment year.

Response: We appreciate the support and acknowledgement of our efforts to provide an ease of transition to the performance threshold for the CY 2024 MIPS payment year.

Comment: One commenter urged CMS to work with Congress on developing a legislative fix to change the statutory requirements for the CY 2024 MIPS payment year performance threshold, believing that because of the PHE for COVID–19, a change may be needed to ease the transition of increasing the performance threshold over time.

Response: We acknowledge the commenter's concern and recommendation. Given that we do not know the magnitude of impact that the PHE for COVID–19 will have on clinician participation in MIPS for the CY 2023 payment year, we believe it would be premature to seek a legislative change at this time. However, we intend to consider these concerns and potentially address them in the future.

Comment: A few commenters expressed their concern with the estimated performance threshold of 74.01 points for the CY 2024 MIPS payment year. One commenter recommended that the performance threshold increase no more than 10 percent year-over-year beginning with the CY 2024 payment year, while another commenter recommended setting the year 6 performance threshold at 75 points, since it is a round number. Commenters stated that the PHE for COVID–19 will continue into the CY 2021 performance period and may cause unforeseen consequences. They urged CMS to use any flexibilities available in setting the performance threshold for the CY 2024 MIPS payment year.

Response: We understand the commenters concern. We understand that both direct and indirect impacts of the PHE for COVID–19 will likely continue into CY 2021. We stated in the CY 2021 PFS proposed rule (85 FR 50318) that in the event that the CY 2019 MIPS performance year data becomes available, with sufficient time to inform our policy decisions for the final rule, we proposed to revisit and potentially revise our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year. However, after analyzing the data for the CY 2019 performance period, we have decided not to revise our prior estimate of the performance threshold for the 2024 MIPS payment year. The statute requires that, beginning with the 2024 MIPS payment year, the performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. The data for the CY 2019 MIPS performance period estimates the mean final score as 79.8 and the median final score as 85.27, which are significantly higher than our prior estimate of 74.01 points for the 2024 MIPS payment year performance threshold. We plan to continue utilizing performance data, as it becomes available, to inform policy decisions in future rulemaking.

After consideration of the public comments received, we are not finalizing our proposal to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized at § 414.1405(b)(8). We are maintaining the performance threshold at 60 points, as previously finalized, at § 414.1405(b)(8). We are also not finalizing our proposal to revisit and potentially revise our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year.

(4) Example of Adjustment Factors

Figure A provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our policies for the 2023 MIPS payment year. In Figure A, the performance threshold is set at 60 points. The applicable percentage is 9 percent for the 2023 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the 2023 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 15 points based on the finalized performance threshold of 60 points for the 2023 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 9 percent for the 2023 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 9 percent. If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be greater than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 60 points (which is the finalized performance threshold) would receive a neutral MIPS payment adjustment. Because the performance threshold is 60 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 9 percent.

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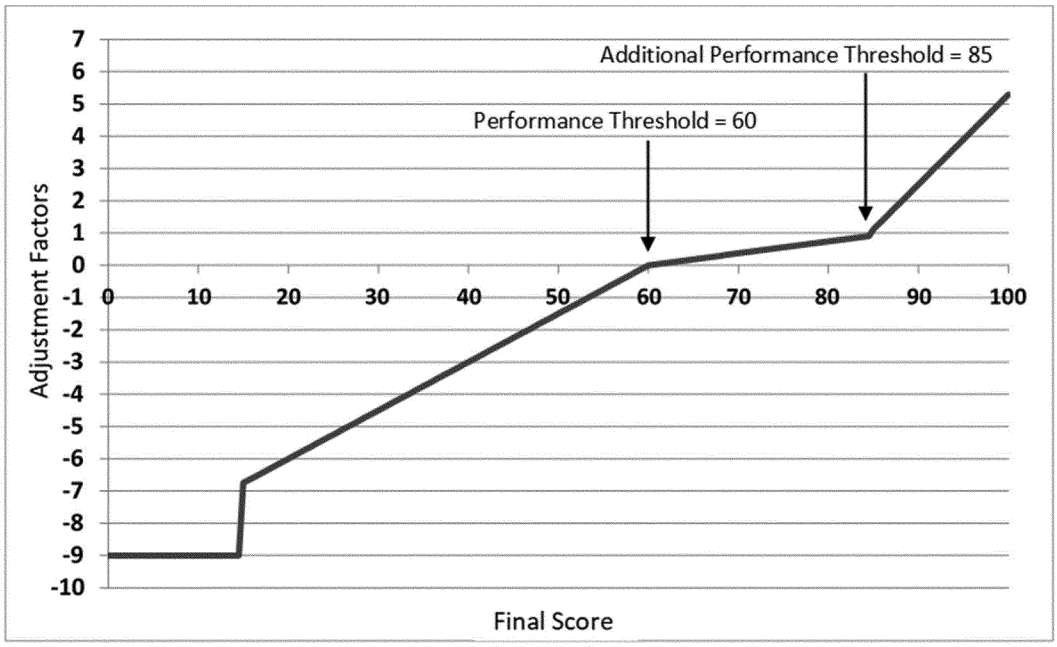
Figure A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2023 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustartive. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is inteded to ensure budget neutrality, but cannot be higher than 3.0. MIPS eligible clinicians with a final score of at least 85 points would also receive an additional adjustment factor for expectional performance. The additional adjustment factor starts at 0.5 percent, cannot exceed 10 percent, and is also mulitiplied by a scaling factor that is greather than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustartive as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 57 illustrates the changes in payment adjustment based on the final policies from the CY 2020 PFS final rule (84 FR 63031 through 63045) for the 2022 and 2023 MIPS payment year, as well as the applicable percent reqired by section 1848(q)(6)(B) of the Act.

TABLE 57: Illustration of Point System and Associated Adjustments Comparison between the Finalized 2022 MIPS Payment Year and the Finalized 2023 MIPS Payment Year

2022 MIPS Payment Year		Previously Finalized 2023 MIPS Payment Year	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-11.25	Negative 9%	0.0-15.0	Negative 9%
11.26-44.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	15.01-59.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
45.0	0% adjustment	60.0	0% adjustment
45.01-84.99.	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	60.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance

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f. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

On July 1, 2018, we provided the first performance feedback for the Quality Payment Program. The second performance feedback was provided on July 1, 2019. However, for this year due to the PHE for COVID–19, we stated in the proposed rule (85 FR 50321) that we may provide performance feedback after July 1, 2020 (that is, performance feedback based on data submitted for the performance period in 2019). We stated that although we aim to provide performance feedback on or around July 1 of each year, it is possible that the release date could be later than July 1 depending on the circumstances. We estimated that we would provide performance feedback in late July or early August, although we noted this timeframe could be subject to change. We directed readers to *qpp.cms.gov* for more information.

On August 5, 2020, we released the third performance feedback for the Quality Payment Program, which was for the 2019 performance period. Additional information is available at *https://qpp.cms.gov/about/deadlines?py=2019*. We received public comments on our expected timeframe for providing performance feedback.

Comment: One commenter noted their appreciation for the updates on the PHE delaying the release of performance year

2019 feedback reports but expressed concern that the online portal for QPP feedback reports is confusing and difficult to navigate. The commenter recommended sharing additional scoring information with MIPS eligible clinicians.

Response: We appreciated the commenters for their feedback and support. We refer readers to *qpp.cms.gov* Resource Library where the 2019 MIPS Performance Feedback Resources user guide details how to access and how CMS scores these reports.

g. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), and the May 8th COVID–19 IFC (85 FR 27594 through 27595) for our previously established policies regarding third party intermediaries.

In the CY 2021 PFS proposed rule (85 FR 50321 through 50331), we proposed to make several changes to requirements for (1) third party intermediaries generally, (2) QCDRs, (3) qualified registries, and (4) remedial action.

(1) Generally

(a) Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We refer readers to § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), and as further revised in the CY 2019 PFS final rule (83 FR 60088) and CY 2020 PFS final rule (84 FR 63049 through 63052) at § 414.1400(a)(2) for our current policy regarding the types of MIPS data that third party intermediaries may submit. Through the CY 2021 PFS proposed rule (85 FR 50321 through 50322), we intended to clarify our requirements of QCDRs, qualified registries, and health IT vendors with regards to submitting data for purposes of the MIPS program through revisions to our regulation codified at § 414.1400(a)(2), particularly for those third party intermediaries who are interested in supporting MVPs in the future. Therefore, we proposed to revise § 414.1400(a)(2) as follows:

Except as provided under § 414.1400(a)(2)(ii), QCDRs, qualified registries, and health IT vendors must be able to submit data for all of the following MIPS performance categories:

- Quality, except:

++ The CAHPS for MIPS survey; and

++ For qualified registries and health IT vendors, QCDR measures;

- Improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*)).

Health IT vendors that do not support MVPs, must be able to submit data for at least one of the MIPS performance categories described above. We requested comments on the proposals.

We received public comments on the proposed requirements for MIPS performance categories that must be supported by third party intermediaries. The following is a summary of the comments we received and our responses.

Comment: One commenter agreed with the requirement that health IT vendors who do not support MVPs must submit data for at least one of the MIPS performance categories. The commenter stated submitting data is necessary for at least the quality category as all vendors need to be certified for submitting the QRDA file.

Response: We thank commenters for their support.

Comment: One commenter supported the reporting exception for QCDRs and qualified registries whose clinicians fall under reweighting policies.

Response: We thank the commenter for their support. For the Promoting Interoperability performance category, we currently reweight clinicians that are non-patient facing, hospital-based or who are one of the NPP types eligible for reweighting. We refer readers to review our reweighting policies at § 414.1380(c)(2).

After consideration of public comments, we are finalizing our policy as proposed at § 414.1400(a)(2).

(i) Reporting MVPs Through Third Party Intermediaries

We refer readers to section IV.A.3.a. of this final rule where we discuss reporting MVPs through third party intermediaries and summarized our proposal that QCDRs, qualified registries, and health IT vendors who support the Quality, Promoting Interoperability, and Improvement Activities performance categories may also support the reporting of MVPs.

(ii) Reporting APM Performance Pathway (APP) Through Third Party Intermediaries

We refer readers to section IV.A.3.b. of this final rule where we reiterate our proposal and include responses to public comments that beginning with the CY MIPS 2023 payment year, MIPS eligible clinicians scored under the APP would be scored on the quality measure set finalized for that MIPS performance period. Three quality measures (Quality ID# 001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%), Quality ID#: 134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, and Quality ID# 236: Controlling High Blood Pressure) were proposed to be reported using the MIPS CQM and eCQM collection types.

(b) Approval Criteria for Third Party Intermediaries

(i) Background

We refer readers to § 414.1400(a)(4), the CY 2019 PFS final rule (83 FR 59894 through 59895, 60088), the CY 2020 PFS final rule (84 FR 63052 through 63053), and the May 8th COVID–19 IFC (85 FR 27594 through 27595) for previously finalized policies related to the approval criteria for third party intermediaries.

(ii) New Approval Considerations—Past Performance and Conduct

During past years of the MIPS program we have encountered third party intermediaries failing to meet program requirements and engaging in other conduct that could harm the integrity of the MIPS program. Some examples of third party intermediaries failing to meet program requirements include, but are not limited to: Failing to meet requirements to submit data for a performance category; failing to provide services throughout the entire performance period and applicable data submission period; and providing data that is not true, accurate, or complete. Additionally, we have also encountered third party intermediaries who have provided inaccurate information to the clinicians and groups they support regarding the obligation to submit data to CMS that are true, accurate and complete. For example, we are aware of third party intermediaries offering services and tools to eligible clinicians that encouraged the selection of misrepresentative data to maximize scores, commonly referred to as ''cherry-picking,'' that would result in the submission of data that did not accurately represent of the clinician's or group's performance.

In preparation for future years of the program, we believe it is important to

disapprove third party intermediaries that have demonstrated their failure to comply with program requirements or have provided inaccurate information regarding MIPS program requirements to clinicians. In the CY 2021 PFS proposed rule (85 FR 50322), we discussed that we are concerned with the potential adverse program effect of this conduct, such as delayed and erratic reporting if third party intermediaries fail to support MIPS reporting for the entire performance period and reporting period, and the possibility of inaccurate data submissions. As a result, we noted that we believe it is important to consider these factors when making determination regarding whether to approve a third party intermediary for future participation in the MIPS program.

Therefore, we proposed to amend the current § 414.1400(a)(4) to add paragraph (a)(4)(ii):

The determination of whether to approve an entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician. We noted that we intend on utilizing all available information to make these approval determinations, including without limitation, information collected through compliance audits under our existing audit authority as described in § 414.1400(g). Third party intermediaries may be selected during the performance period to be audited for a given requirement. As a part of our outreach to a selected third party intermediary, we intend on providing additional direction with regard to the timeline and information needed for the audit. The results of the audit will be reviewed to inform future approval of a third party intermediary, and if remedial action is warranted, we noted that we will utilize our existing authority as described in § 414.1400(f). We believe use of this information in approval determinations will help reduce the risk of third party intermediaries that are unreliable, thereby avoiding a possible increase in burden to clinicians who may inadvertently select an unreliable third party intermediary for purposes of reporting for the MIPS program. We requested comments on the proposals; specifically, on whether there are other factors that should inform our considerations when approving third party intermediaries.

The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposal to take into account past performance and conduct when determining whether to approve an entity as a third party intermediary for a MIPS performance period. However, commenters requested that CMS clarify that an entity which may have failed to comply with a requirement of the MIPS program will not result in automatic disqualification as a third party intermediary for a future MIPS performance period if that entity has entered into an CMS approved Corrective Action Plan.

Response: We thank commenters for their support.

We also clarify that this policy does not establish that particular conduct or the existence of a Corrective Action Plan would automatically disqualify a third party intermediary from approval in a future performance year. Rather, this policy establishes that failure to comply with the requirements of this section for any prior MIPS payment year is a factor the agency may take into account when making a determination of whether to approve an entity as a third party intermediary for a MIPS performance period. We generally do not anticipate that conduct for which CMS has approved a Corrective Action Plan standing alone would be the basis for CMS not approving the TPI for participation in a future MIPS Performance period.

After consideration of public comments, we are finalizing our policy as proposed at § 414.1400(a)(4).

(iii) Third Party Intermediary Training and Support

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77374) and (81 FR 77384 through 77386), we established our expectation that QCDRs and qualified registries perform certain functions related to data submission. One of those expectations is participation in ongoing support conference calls hosted by CMS (approximately one call per month) and an in-person kick-off meeting (if held) at our headquarters in Baltimore, MD. (81 FR 77368) and (81 FR 77384). The purpose of these meetings is to provide approved QCDRs and qualified registries program updates from subject matter experts who work across the Quality Payment Program. At these meetings, CMS subject matter experts and our contractors provide approved QCDRs and qualified registries with updates, answer questions, and provide technological demonstrations. In light of the PHE for COVID–19 and consistent with the goal of infection control, we reevaluated our expectations and have decided to adopt a policy allowing for flexibility moving forward. With the health and safety of our stakeholders in mind, we noted that we believe virtual meetings would be sufficient when in-person meetings are not possible. We proposed to codify these expectations in a proposed requirement at § 414.1400(a)(4)(iii) that third parties intermediaries participate in an annual meeting and training calls as deemed necessary by CMS.

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we stated our expectations for health IT vendors that serve as third party intermediaries by obtaining data from the CEHRT of a MIPS eligible clinician and submitting such data to CMS for participation in MIPS. For further discussion of CEHRT, we refer readers to sections III.M.3 and IV.A.3.g.(1)(iv) of this final rule. Because the submission requirements and policies that may be added or modified from year to year have the potential to alter expectations for all third party intermediaries, we believe that mandatory meetings and training calls would also be appropriate for health IT vendors that will serve as third party intermediaries. Hosting training calls for health IT vendors would give us an opportunity to provide a review of requirements, answer questions, and explain updates to the annual submission process and other policies as applicable. Thus, we proposed the requirement that third party intermediaries participate in an annual meeting and training calls as deemed necessary by CMS including those third party intermediaries that are health IT vendors. We solicited comments on the best method to reach health IT vendors so that we can invite them to required meetings and share additional information. We noted that we are considering listserv communications through the QPP listserv but would welcome suggestions for other communication mechanisms.

We previously finalized the CMS-approved survey vendor approval criteria in § 414.1400(e) as discussed in the CY 2018 PFS final rule (83 FR 59907 through 59908). Among the approval criteria, § 414.1400(e)(3) established the requirement that the entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors. In the CY 2021 PFS

proposed rule, (85 FR 50323), we noted that we continue to believe these previously finalized requirements are of importance to CMS-approved survey vendors, such as CAHPS for MIPS vendors. In addition, because the submission requirements and policies that may be added or modified from year to year have the potential to alter expectations for all third party intermediaries, we noted that we believe that the proposed requirement that third parties intermediaries participate in an annual meeting and training calls as deemed necessary by CMS should also be applicable to CMS-approved survey vendors.

In summary, we believe making support calls and trainings mandatory for all third-party intermediaries will provide an abundance of value to all approved third party intermediaries themselves, as well as to the MIPS program and the clinicians who rely on third party intermediaries to make complete, accurate, usable and timely data on their behalf. We believe uniformly codifying this language is appropriate to hold all third party intermediaries accountable for the training and support. Therefore, we proposed to codify at § 414.1400(a)(4)(iii) that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS. We affirmed that, in addition to the obligations under this policy, CMS-approved survey vendors must also continue to meet the requirements at § 414.1400(e)(3).

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal for health IT vendors to be required to attend monthly training and support calls and requested additional opportunities to attend trainings and ask questions.

Response: We thank the commenter for their support for Health IT vendor training. We believe participation in training and support sessions will be very beneficial and educational for health IT vendors. CMS agrees that regular dialogue is an important element to help vendors receive the latest information and reminders and to give third party intermediaries the best opportunity for success of the vendor and their clinician participants. For clarification, the requirement, which applies beginning with the 2021 MIPS performance year/2023 MIPS payment year does not specifically establish mandatory monthly calls for health IT vendors but rather establishes that attendance and completion of training and support sessions will be ''in the form and manner, and at the times, specified by CMS''. We will take into account the commenter's suggestion that training opportunities for health IT vendors should be more frequent than monthly when developing these training and support sessions.

Additionally, we did not receive comments on our proposal to message health IT vendors the same way that that we message to other third party intermediaries by utilizing our listserv communications through the QPP listserv. We are adopting this approach to communication with health IT vendors and encourage health IT vendors, if they have not already, to sign up for listserv messages at *https://qpp.cms.gov/.*

Comment: One commenter supported the proposal to require QCDRs and qualified registries to attend training and support calls.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposals as proposed.

(iv) Future Safeguards for All Third Party Intermediaries

We understand our obligation to ensure the integrity of the MIPS program and will continue to assess opportunities to strengthen program safeguards. Certain safeguards apply to all third party intermediaries, including those described in § 414.1400(a), (f), and (g). In sections IV.A.3.g.(2)(a) and IV.A.3.g.(3) of the CY 2021 PFS proposed rule, we proposed additional program safeguards in regard to data validation audit and targeted audit requirements that would apply specifically to QCDRs and qualified registries. As discussed there, the proposals would require QCDRs and qualified registries to conduct validation on data prior to the data being submitted to CMS for purposes of the MIPS program. We limited those proposals to QCDRs and qualified registries, but we solicited feedback on expanding the proposed requirements to all third party intermediaries through future rulemaking. We refer readers to sections IV.A.3.g.(2)(a) and IV.A.3.g.(3) in this final rule for a discussion of our finalized policies.

The Office of the National Coordinator for Health Information Technology's (ONC) Health IT Certification Program provides for the certification of certain health IT. The requirements for ONC certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary. The Quality Payment Program adopted a definition of certified electronic health record technology (CEHRT) at § 414.1305.

For a discussion of the updates to 2015 Edition certification criteria referenced in the CEHRT definition adopted for the Quality Payment Program, we refer readers to section III.M. of the CY 2021 PFS proposed rule (85 FR 50323) and section IV.A.3.c.(4) of this final rule.

It is important to note that a health IT vendor which acts as a third party intermediary for purposes of the MIPS program may or may not be the same entity as a health IT developer which certifies health IT products as part of the certification program. While health IT developers may act as third party intermediaries for their customers, other service providers who do not develop health IT products may also assist MIPS eligible clinicians by submitting data obtained from CEHRT on their behalf and thereby function as a health IT vendor for purposes of the MIPS program. Furthermore, the entities that are not health IT developers must only submit data on behalf of eligible clinicians that has already been captured and calculated using the functions of CEHRT. Unlike QCDRs and qualified registries, third party intermediaries that are health IT vendors may or may not also possess expertise related to quality improvement and analysis/validation of clinical quality data, and we do not currently require these organizations to attest that they possess these capabilities.

We are increasingly aware of data integrity issues that have impacted data submitted by health IT vendors that obtain data from MIPS eligible clinician's CEHRT and serve as third party intermediaries to submit this data on behalf of MIPS eligible clinicians. We are aware of instances in which health IT vendors have submitted data that are inaccurate and unusable. These data issues may result in improper payments or otherwise undercut the integrity of the MIPS program. In some instances, data issues caused by health IT vendors may have downstream negative impacts to the clinicians whose data the health IT vendor is submitting, such as negative payment adjustments and inaccurate data publically posted on the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Although we did not propose to add data validation requirements for health IT vendors in the proposed rule, we noted that we were considering ways to

impose such requirements in the future. We solicited comment on whether we should impose data validation requirements on health IT vendors as part of the third party intermediary approval process and if so, how the data validation requirements for health IT vendors should differ, if at all, from those we proposed for QCDRs and qualified registries. We noted that we believe that potentially requiring health IT vendors to validate the data they submit to us for purposes of the MIPS program will lead to the submission of data that can be considered more reliable and accurate. Therefore, we sought comment on the future application of such requirements on health IT vendors and if there are factors unique to health IT vendors that should be considered when developing such a policy. We also sought comments on: Whether health IT vendors currently submitting data on behalf of MIPS eligible clinicians possess the capabilities to engage in the data validation processes we proposed for QCDRs and Qualified Registries; the burden on health IT vendors of adopting the data validation requirements as proposed for QCDRs and qualified registries and whether the imposition of these requirements on health IT vendors would discourage health IT vendors from serving as third party intermediaries; whether alternative requirements for health IT vendors would impose less burden on these third parties' intermediaries while still ensuring that the data submitted is accurate and complete; and how any future data validation processes should impact certification under the ONC Health IT Certification Program for health IT developers who also serve as a health IT vendor third party intermediary for the purposes of MIPS.

For CMS-approved survey vendors, such as CAHPS for MIPS vendors, we did also not propose any new data validation requirements. In the CY 2018 PFS final rule (83 FR 59907 through 59908) we previously finalized requirements at § 414.1400(e) that address the validity of data submitted to CMS for CMS-approved survey vendors. Specifically, we previously finalized at § 414.1400(e)(4) that as a condition of approval the entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts. We noted that we believe this previously finalized requirement at § 414.1400(e) is sufficient to address potential concerns about the accuracy of data submitted by survey vendors; however, we solicited feedback on whether the audit requirements in the proposal should be expanded to include survey vendors.

The following is a summary of the comments we received on potential future notice-and-comment to impose new data validation requirements on health IT vendors and CMS-approved survey vendors and our responses to those comments. We refer readers to sections IV.A.3.g.(2)(a) and IV.A.3.g.(3) in this final rule for a discussion of comments and responses to our current proposed policies for data validation by QCDRs and qualified registries, respectively.

Comment: Several commenters supported future requirements for health IT vendors to perform data validation. One commenter believes that it is the responsibility of the health IT developer to ensure the validity of the data their CEHRT is producing, and that a health IT developer's certification should be tied to its ability to capture and calculate data accurately. Another commenter believes that any entity that is submitting data on behalf of a clinician to CMS (for example, QCDR or health IT vendor) should be held to the same data validation requirements of a QCDR and without these requirements, the two different standards for registries and health IT vendors would undermine the goal of standard data integrity and place increased financial burden on non-profit QCDRs above that of health IT vendors.

Response: We appreciate the support and believe additional data validation could help to promote health IT vendor accountability for the accuracy of the data they submit to CMS. We have shared with ONC the commenter's support for any future data validation process impacting certification under the ONC Health IT Certification Program for health IT developers who also serve as a health IT vendor third party intermediary for the purposes of MIPS.

Comment: Several commenters did not support health IT vendors being required to perform data validation. These commenters believe CMS requirements for data validation by health IT vendor third party intermediary for the purposes of MIPS would be costly and burdensome and duplicative and unnecessary in light of the oversight these health IT vendors receive under the ONC regulatory framework, including the recently adopted Real World Testing requirement under the 21st Century Cures Act. One commenter requested that CMS monitor results of the Condition and Maintenance of Certification Real World Testing requirement prior to proposing requirements in MIPS. Another commenter requested that if CMS undertakes imposes additional requirements in MIPS for health IT vendors to validate data submitted on quality measures, the CMS requirements should replace work already required by ONC through the ONC certification program and real world testing, to avoid duplicative efforts.

One commenter stated that health IT developers already have to certify to each measure they offer as an eCQM and will soon be required to meet real-world testing requirements under the new Conditions and Maintenance of Certification provisions which should include testing based on current year measure specifications for the eCQM criteria. The commenter further believes that centrally validating eCQM data can be difficult because eCQM data collection can vary between each health IT developer and potentially between every provider organization depending on how a system is implemented by the provider organization. The commenter also expressed its concern with who would need to meet the eCQM data validation requirements, when they would need to meet the requirements, and for what measures the validation would need to be performed. The commenter requested that CMS work with the Electronic Health Record Association (EHRA) and its members to outline potential options for validation of measures as it relates to HIT Developers and encouraged CMS to consider means by which these requirements may be met by other activities the health IT developer is engaged in for meeting the Conditions and Maintenance of Certification such as by real-world testing. Another commenter requested CMS differentiate between developers of certified health IT and other health IT vendors due to their belief that that developers of certified health IT inherently already performs data validation.

Response: We appreciate the commenters' concerns regarding potential overlap between potential CMS data validation requirements for a health IT vendor third party intermediary for the purposes of MIPS and existing policies for oversight of health IT developers. We agree that any new data validation requirements for health IT vendors that submit data to CMS as third party intermediaries should take into account existing requirements designed to ensure these entities enable accurate reporting of data. As part of this effort, we plan to consider the real world testing Condition of Certification finalized

under ONC's 21st Century Cures Act final rule (85 FR 25765), which focuses on how certified health IT functionality is deployed in real-world settings and could potentially include activities related to validation of data reported using certified health IT. We understand that ONC's requirement does not necessarily require validation of data reported to CMS using certified health IT. Rather, we understand that the ONC condition of certification allows developers the flexibility to select measures to demonstrate how their certified health IT products function in real world environments. While data validation of eCQMs could conceivably be used as part of those real-world testing measures, we do not believe it is not a requirement to meet the Condition of Certification. We also appreciate the suggestion that CMS work with stakeholders, and plan to reach out to both health IT vendors and other interested parties prior to further action on new requirements to identify ways to minimize burden and align with existing programs.

As noted above, we will continue to work with ONC going forward as we consider any future rulemaking in this area.

Comment: One commenter did not support future requirements for CAHPS survey vendors to conduct data audits due to its belief that it would be burdensome and potentially duplicative given that CAHPS vendors are currently required to adhere to established quality control processes as outlined in the Quality Assurance Guidelines (QAGs) for each survey administration which include the requirement to maintain and submit a Quality Assurance Plan to CMS' subcontractor on an annual basis; keep records of CAHPS for MIPS quality assurance activities; and participate in other CAHPS Survey oversight activities, which can include auditing of submitted data, on-site visits and/or conference calls, and other activities as instructed by CMS.

Response: We agree with the commenter. We believe our previously finalized requirement at § 414.1400(e) is sufficient to address potential concerns about the accuracy of data submitted by survey vendors, and do not anticipate adding any new data validation requirements for CAHPS for MIPS vendors.

(2) Qualified Clinical Data Registries (QCDRs)

We generally refer readers to section 1848(m)(3)(E) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013), which requires the Secretary to establish requirements for an entity to be considered a QCDR and a process to determine whether or not an entity meets such requirements. We refer readers to section 1848(m)(3)(E)(i)(v) of the Act, the CY 2019 PFS final rule (83 FR 60088), the CY 2020 PFS final rule (84 FR 63053 through 63058), May 8th COVID–19 IFC (85 FR 27594 through 27595) and § 414.1400(a)(4) through (b) for previously finalized policies about third party intermediaries generally and QCDRs specifically. In the CY 2021 PFS proposed rule (85 FR 50324), we proposed a technical update to § 414.1400(b) title to rename it from ''QCDR approval criteria'' to ''QCDRs'', to better align the title with the content of the regulation. In addition, we proposed policies related to QCDR: (1) Data validation audits and targeted audits; and (2) measure requirements.

(a) Data Validation Audit and Targeted Audit Requirements

In the CY 2017 Quality Payment Program final rule, we discussed our expectation that QCDRs and qualified registries would conduct validation on the data they intend on submitting for the MIPS performance period (81 FR 77366 through 77367) and provide the results of the data validation to CMS in the form of a data validation execution report by May 31st of the year following the performance period. Our intention was to establish our expectation that QCDRs would establish a process to assess whether the data are true, accurate, and complete prior to submitting them to CMS for purposes of the MIPS program. We noted that we believe it is important to establish a requirement that QCDRs conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. In instances where a QCDR discovers data are inaccurate or incomplete, the entity must correct the issue prior to submitting the data to CMS in order to provide accurate certification in accordance with § 414.1400(a)(5). A QCDR that submits a false certification submits data that is inaccurate, unusable or otherwise compromised to CMS for purposes of the MIPS program may be subject to remedial action or termination under § 414.1400(f). We also noted that we believe requiring QCDRs to validate the accuracy of the data they are submitting is an important safeguard to promote accurate payments under the MIPS program. Therefore, we proposed to codify at § 414.1400(b)(2)(iv) and (v) requirements beginning with the 2023 MIPS payment year as condition of approval each QCDR must conduct annual data validation audits and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits. We also proposed specific obligations for those audits as discussed below.

- We proposed to codify at § 414.1400(b)(2)(iv)(A), that the QCDR must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program. We believe it is important for QCDRs to conduct validation audits to identify and fix concerns regarding data accuracy prior to submitting data to us, including potential issues related to data aggregation and calculation. Conducting the data validation prior to data submission will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete. In the CY 2017 Quality Payment Program final rule, we described this auditing using the term randomized audit (81 FR 77366). We proposed instead to refer to this audit as the data validation audit in an effort to be abundantly clear regarding our expectations that the QCDR will purposefully construct a sample and conduct an audit that complies with specific regulatory requirements and also to distinguish these audits from the targeted audits discussed below and proposed at § 414.1400(b)(2)(v).
- We proposed to codify at § 414.1400(b)(2)(iv)(B), the QCDR must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories. We believe that it is important that data validation is performed across all performance categories for which the QCDR submits data since QCDRs must attest that data submitted to CMS is true, accurate, and complete and data for each of these performance categories can influence score calculation and payment adjustments.
- We proposed to codify at § 414.1400(b)(2)(iv)(C), that the QCDR must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants. We believe it is important for the data submitted to CMS be accurate for all clinicians and groups for which the QCDR intends on submitting data to the MIPS program, regardless of whether they are required to participate, have opted in, or have chosen to voluntarily participate.

Therefore, we proposed to require that the data validation audits should account for all types of submitters that are utilizing the QCDR to submit data to CMS for purposes of the MIPS program. We noted the importance of validating data for all submitter types regardless of its use for payment or public reporting. Even clinicians who voluntarily report to MIPS and whose data are not used for payment purposes could have their data publically posted on the Physician Compare website. We noted that we believe all data the QCDR submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.

• We proposed to codify at § 414.1400(b)(2)(iv)(D) that the QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. If the data a QCDR intends to submit to CMS for purposes with the MIPS program are to demonstrate that a clinician did a particular clinical activity or achieved a particular clinical outcome, we noted that we believe meaningful validation of such data requires the QCDR to use clinical documentation to confirm that the activity occurred or was performed.

• We proposed to codify at § 414.1400(b)(2)(iv)(E) that the QCDR shall conduct each data validation audit using a sampling methodology that meets the following requirements:

++ Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR may use a sample size of 50 TIN/NPIs.

++ Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

We believe the aforementioned sampling methodology is appropriate for multiple reasons. First, the sampling methodology criteria are consistent with the methodology established under the legacy Physician Quality Reporting System (PQRS) program and as described in the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367). As this methodology has been used for many years under the legacy program, we believe stakeholders are well versed in executing data validation audits using this sampling methodology. Second, the proposed methodology accounts for QCDRs and qualified registries of varying sizes. Data validation requires a level of effort on the part of the QCDR to execute a data validation plan, identify a sample, and collect information for purposes of chart review; therefore, we are cognizant that requiring a larger sample size would create additional burden on QCDRs and clinicians to account for a larger volume in TIN/NPIs and medical records for review.

• We proposed to codify at § 414.1400(b)(2)(iv)(F) that each QCDR data validation audit must include the following:

++ Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant. We believe that it is important for the QCDR to track the eligibility status of each clinician and group that wishes to use a third party intermediary to report, because accurate information regarding eligibility is important to ensuring payment adjustments are properly applied. Furthermore, verification of eligibility status is consistent with the requirement for QCDRs to track opt-in participants, as described at § 414.1400(a)(4)(iv) and in the context of clinicians who voluntarily report to MIPS helps ensure the accuracy of data publically posted on the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

++ Verification of the accuracy of Tax Identification Numbers (TINs) or National Provider Identifiers (NPIs). Correct TINs and NPIs are critical to ensure data submitted by the QCDR are attributed to the correct clinicians and groups. Inaccurate NPIs or TINs may lead to inadvertent downstream impacts to the way clinicians and groups are scored, and assigned a payment adjustment.

++ Calculation of reporting and performance rates (for example, formulas included in the quality measure specifications). QCDRs must follow the measure specifications when calculating reporting and performance rates. Calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure data are consistent, reliable, and have been calculated in a uniform manner.

++ Verification that only MIPS quality measures and QCDR measures that are relevant to the performance period will be utilized for MIPS submission. Measure specifications for the MIPS quality measures and QCDR measures go through maintenance on an annual basis. Use of outdated measure specifications would likely result in the QCDR submitting inaccurate or compromised data for the clinicians and groups they support. While not all measures go through substantive changes on an annual basis, there are changes to codes that do occur annually that should be accounted for when programing measures. Therefore, we noted that we believe it is important that QCDRs are utilizing the most current version of the measure specification, relevant to the performance period in which they are participating.

• We proposed to codify at § 414.1400(b)(2)(iv)(G), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. We noted that we believe it is important that the results of the data validation be shared with us in order for us to understand the types of issues the QCDRs have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education. It is our belief that the report will be largely comprised of issues that were identified and resolved. However, if an issue has been identified and could not be resolved, we would want to understand what the issue is and why it could not be resolved. We emphasized that all data submitted to CMS by a QCDR on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge as described in § 414.1400(a)(5). If a QCDR submits a false certification or data that are data that are inaccurate, unusable, or otherwise compromised, the QCDR may be subject to remedial action or termination as described at § 414.1400(f).

• We proposed to codify at § 414.1400(b)(2)(v)(A), that if a data validation audit under § 414.1400(b)(2)(iv) identifies one or more deficiency or data error, the QCDR must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year. We noted that we believe targeted audits are important to further evaluate the impact of deficiencies or data errors to the cohort of clinicians

and groups that the QCDR intends to submit data for, and for QCDRs to determine the reason the deficiency or data error occurred.

• We proposed to codify at § 414.1400(b)(2)(v)(B), that the QCDR must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year. To promote the accuracy of the data submitted to the MIPS program for the payment year and to reduce the risk that the agency initiates payment calculations in reliance on inaccurate data, it is important for the QCDR to conduct required targeted audits and correct any deficiencies and data errors identified through those audits prior to submitting the data to CMS.

• We proposed to codify at § 414.1400(b)(2)(v)(C), the QCDR must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(2)(iv)(E). The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

We noted that we believe the sampling methodology we proposed for data validation audits is equally appropriate for the conduct of targeted audits. We believe that adopting the same methodology for both audit types would be less burdensome on QCDRs than requiring these entities to apply a separate sampling methodology for their targeted audits. Provided that data in the sample for the targeted audit does not overlap with the data that was reviewed in the data validation audit, we believe the targeted audit would provide the QCDR with a reasonable perspective into impact and root cause of deficiencies and data errors across the data to be submitted without imposing the burden that would result from maintaining a separate sampling methodology for targeted audits.

• We proposed to codify at § 414.1400(b)(2)(v)(D), in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected. As is the case with the results of data validation audits, we noted that we believe it is important that the results of the targeted audits be shared with us in order for us to understand the types of issues the QCDRs have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education.

We requested comments on the aforementioned proposals, including whether stakeholders are concerned with implementing the policies for the 2023 MIPS payment year, and if so, what barriers do they believe they would face in implementing these requirements.

The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to require data validation audits and targeted audits.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposal to require QCDRs to be held accountable to report on and correct QCDR measure logic issues or other errors generated by the QCDR.

Response: We clarify that the proposed data validation requirements for QCDRs is not targeted specifically to errors generated by the QCDR but rather to more broadly help ensure the data submitted to CMS by QCDRs is true, accurate and complete.

Comment: Some commenters stated that while they can advise the eligible clinician or group to correct their documentation practices or workflow errors, they cannot hold them accountable to act and at the point in the performance year at which this audit occurs, the QCDR will already be contractually bound to report for the eligible clinician or group based on CMS required agreements. Other commenters believe that CMS should take responsibility for disciplining eligible clinicians that refuse to make data corrections or participate in focused reviews and implement a proposal regarding such clinicians which would allow registries to submit their data, along with notification of their refusal(s).

Response: We disagree with the commenter's suggestion that CMS requires third party intermediaries to enter into agreements that would contractually bind the third party intermediary to submit data to CMS for the eligible clinician or group that the third party intermediary knows the data are not true, accurate and complete. All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Therefore, in instances where a QCDR determines there is no documentation to support that a given quality action or activity was completed, the QCDR should advise the eligible clinician or group to correct their documentation practices and workflows, and the QCDR must also refrain from submitting inaccurate data to CMS. If a third party intermediary determines that the data it received for a clinician is not true, accurate or complete, and the clinicians refuse to correct the error, then the a third party intermediary should not submit the inaccurate data on their behalf. We emphasize that we do not want inaccurate data submitted to us, and we do not want a third party intermediary to submit incorrect data on behalf of non-compliant clinicians. Furthermore, as described in the CY 2020 PFS final rule (84 FR 63023 through 63027), if we determine a MIPS eligible clinician has knowingly submitted compromised data for a performance category the clinician's performance category score would be zero and the scoring weight for the category will not be redistributed. A third party intermediary that submits inaccurate data to CMS, may be subjected to the remedial action and termination under § 414.1400(f) even in instances where clinicians refuse to correct the data.

Comment: One commenter requested CMS provide a standardized process for third party intermediaries to disclose of issues prior to and after data submission.

Response: While we appreciate the commenter's request for a standardized process for third party intermediaries to disclose data issues, we believe some flexibility is needed to accommodate the range of scenarios that arise. We will issue guidance on how QCDRs and qualified registries should operationalize the required reporting on the results of each data validation audit and targeted audit in which identified data issues that have arisen prior to submission and have been corrected should be described. To disclose data issues identified in other contexts, a third party intermediary should submit a ticket to the Quality Payment Program Service Center by phone: 1–866–288–8292 (TRS: 711) from Monday–Friday, 8 a.m.–8 p.m. eastern standard time, or may contact the QPP Service Center by email: *QPP@cms.hhs.gov.*

QCDRs must disclose of data issues as a part of their data validation execution report. Furthermore, QCDRs are required to conduct this validation prior to submitting the data to CMS, so that

data issues may be identified and corrected. As a reminder, all QCDRs must follow the data validation audit and targeted audit requirements at § 414.1400(b)(2)(iv) and (v).

Comment: Several commenters believe that CMS should not require collection of more protected health information (PHI) than is necessary to achieve its purpose due to their concern that the codification of multiple auditing requirements related to clinical documentation and patient information could jeopardize their business models and trust with clinicians. The commenters also expressed their belief that CMS should narrowly define what should be collected via an audit, with such criteria preserving the confidentiality of patient information and not subjecting QCDRs to additional risks that they would not otherwise assume. One commenter believes that many QCDRs do not receive PHI from their participants; rather, the participants submit PHI to vendors engaged by the registry and vendors subsequently submit de-identified data to the QCDR for MIPS reporting.

Response: We do not believe that the requirement proposed at § 414.1400(b)(2)(iv)(D) would improperly increase risk to the confidentiality of patient information. Collection standards established for QCDRs are consistent with program audit requirements already established and there is no indication that this creates additional risks. CMS respects patient privacy and will not use or disclose PHI except as permitted by applicable privacy and security laws, including, but not limited to, the HIPAA Privacy Rule. Third party intermediaries are generally required to have HIPAA compliant business associate agreements with any HIPAA covered entities for which they create, receive, maintain, or transmit PHI. This should help mitigate concerns regarding receiving or viewing provider's patient's PHI during an audit.

Comment: A few commenters believe that the requirement to audit a 3 percent sample, and, if an error is found, the requirement to audit an additional 3 percent sample that excludes any TINs/NPIs from the original sample to ensure the error is corrected creates undue burden and the sample size of NPIs and TINs and number of patients per measure required for an audit should be reduced. One commenter believes that since the nature of an error can vary widely and not all types of errors require such an intensive and resource-heavy re-sampling in order to ensure that data is error free, QCDRs should be allowed to determine the most effective and efficient manner through which they can determine the scope and root cause of any errors found in the data validation audit. Another commenter believes that either the random sample/percentage of overall users methodology or the proposal to require data validation for each submitter type be included in the data validation and audit requirements, but not both.

Response: While we understand the level of effort associated with data validation, we disagree that this causes undue burden. We believe that it is critically important that all data submitted is true, accurate and complete and all data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge (§ 414.1400(a)(5)). To help ensure that the data is true, accurate and complete we believe it is important to have data validation and as appropriate audits. Ensuring data integrity and accuracy is critical for the QPP feedback, payments and public display of the data. The sampling requirements reflect our effort to minimize the burden while ensuring a meaningful assessment of the data. We believe it is appropriate for the sampling requirements for the targeted audit to include data from the sample used for the data validation audit in order to determine the scope of the impact of the data errors on those that are choosing to use the QCDR to report. Despite the commenter's suggestion that the size of the targeted audit sample be left to the discretion of the QCDR based on the nature of the error identified in data validation, we do not believe the sample size for the targeted audit should be different from the sample size for the data validation audit. Furthermore, we do not believe it should be at the QCDR's discretion which performance categories of the data submission should be audited. If a clinician is selected for auditing through the sampling methodology, they should be audited in a manner that is objective and considerate to all performance categories in which they have submitted data. As described in the CY 2021 PFS proposed rule (85 FR 50325), the aforementioned sampling methodology has been used for many years under the legacy program, and in the first few years of the MIPS program. We do not believe a smaller sample size for the targeted audit would provide us with an understanding of the impact of the error. In addition, we disagree with the commenter who suggested that the samples used for data validation and targeting audits should not include both a minimum number of users and users of each submitter type. We believe that the samples should account for both of volume and user type in order to promote data accuracy across both these factors. We note, however, that the sample size requirements do include flexibility to reduce burden, including for example establishing that the sample size for each data validation and targeted audit does not need to include more than 50 TIN/NPIs. Therefore, we believe these sampling thresholds strike the right balance of being reliable for both large and small QCDRs and do not impose an undue burden on QCDRs.

Comment: A few commenters requested clarification regarding the calculation of sample sizes for the data validation audits and targeted data audits including: Whether ''TIN/NPI'' is referencing TIN–NPI combinations or is meant to be read as ''TIN or NPI''. Commenters also requested clarification on whether separate sample universes are required for the total number of NPIs and the total number of TINs that the QCDR submits data for; whether the sample universe can simply be based on 3 percent of the total number of TINs that a QCDR submits data for, or is the intention that the 3 percent sample size should be calculated based on the total number of unique TIN/NPI combinations, while also taking into account the minimum and maximum range requirements (for example, a minimum of 10 TIN/NPIs and a maximum of 50 TIN/NPIs); and whether the sample size of 25 percent of patients audited must be based on the total patient population for each TIN selected in the 3 percent sample or is the intention that the 25 percent of patients should be calculated based on the total number of unique TIN/NPI combinations, while also taking into account the minimum and maximum range requirements (for example, a minimum of 5 patients and a maximum of 50 patients). One commenter requested clarification and guidance on the requirement to use a 3 percent sample for targeted data audits separate from the original 3 percent sample used for data validation when an error is found.

Response: To clarify our sample sizes for data validation, the sampling methodology described in our proposal and above requires the use of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, unless that 3 percent sample would result in fewer than 10 TIN/NPIs, which would require the QCDR to use at least 10 TIN/NPIs. The three percent sample size requirements is based on the QCDR's

total number of unique TIN/NPI combinations; we are not requiring two separate samples based on the number of TINs or NPIs separately. If the 3 percent sample would result in more than 50 TIN/NPIs, the QCDR may limit their sample size to 50 TIN/NPIs. For each TIN/NPI selected as a part of the auditing sample, the QCDR must audit 25 percent of the patients, with a minimum of 5 patients and a maximum of 50 patients. For example, if under a unique TIN/NPI combination a clinician has 1000 patients for a particular measure, the QCDR will only need to audit a maximum of 50 charts for this TIN/NPI for this measure. If they only have 10 patients for the given measure, the QCDR would need to review the minimum of 5 charts. In the case of 100 patients reported for a specific measure, the QCDR would need to review 25 charts.

To address what we mean by unique TIN/NPI combinations, unique combinations are how we refer the combination of identifiers used when a specific clinician (that is, NPI) is in a specific practice (that is, TIN). For example, a clinician could work under Group X for 2 days in a week and for Group Y for the remaining days in the week, this would likely result in 2 different unique TIN/NPI combinations, due to the NPI being unique to the clinician and the TIN being unique to the respective group.

The sampling methodology must be used to derive a sample for data validation. If an error was identified through the data validation audit, it would trigger the third party intermediary to conduct a targeted audit. The third party intermediary must use a sample for the targeted audit that does not include data that was used for the data validation process audit in which the error was identified. The third party intermediary must use the sampling methodology to ensure their sample size meets the requirements for the targeted audit.

Comment: One commenter stated that the proposals regarding data validation audits would be especially cumbersome and burdensome with regard to the data of anesthesiologists due to the nature of how the specialty is practiced. The commenter stated that quality measures for anesthesiologists may be derived from data from multiple sources and some practices may collect quality data on paper or practice in numerous locations. Several commenters expressed their concerns with the proposal to require auditing of the Improvement Activities and Promoting Interoperability performance categories and that meaningful validation of what constitutes compliance may vary from one group to another. The commenters suggested that CMS provide additional guidance, as well as allow flexibility to account for the difficulty in validating information often tracked outside of a clinician's EHR, varying practice conditions and constraints that may be present when completing an audit, and the large percent of clinicians who manually enter data late in the fourth quarter.

Response: We thank commenters for their feedback. We understand that data to support the performance of a quality action within a measure may rely on multiple data sources, and the need to for clinicians, such as anesthesiologists, to consistently document the clinical action during each patient encounter, to demonstrate the quality action has been completed. However, we believe that data validation is important to ensure that the quality actions have been truly completed by the clinicians. In light of this, we plan to devote one of the upcoming support conference calls to data validation for the Promoting Interoperability and Improvement Activities performance categories. We will provide guidelines and give participants the opportunity to ask questions.

While recognizing that underlying data submission for performance categories may differ among the clinicians and groups for whom the QCDRs and qualified registries submit data, compliance by a QCDR or qualified registry with its obligation to validate the data should not vary significantly from one group to another. As it relates to the validation of information potentially tracked outside of a clinician's EHR, practice conditions, or systemic constraints due to manual data entry, we believe the required parameters for data validation and targeted audits allow sufficient flexibility to account for this data variation.

Comment: One commenter expressed concern regarding the validation of electronic measures citing its belief that the process for calculating and auditing these measures is different from manually abstracted measures because electronic measures do not consider clinician notes, audio, images, videos, and other non-computable aspects of the chart in their calculation and therefore, could fail an audit if the chart review included areas of the chart not included in the eCQM specification. The commenter also requested additional clarity regarding the term ''chart review.'' The commenter stated that chart review should be defined as a review of the chart data which applies to the measure specification and is available in the manner necessary for the measure calculation process (electronic or human abstraction). The commenter also cited examples of errors (such as a clinician incorrectly documenting a case by entering conflicting information in the clinical note from the discrete, electronic data fields which make up the measure specification, or the EHR storing data in an incomprehensible manner) as areas of a chart that the commenter stated should not be considered in the chart review.

Response: We agree that the measure specification and associated data source are useful guides for implementing audits that meet the data validation requirements. The QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. The eCQM specifications define the data elements in the measure logic and ''calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure data are consistent, reliable, and have been calculated in a uniform manner.'' We remind the commenter that QCDRs and qualified registries must perform a data validation audit to identify data errors prior to data submission to CMS, such as conflicting documentation within the medical chart. QCDRs and qualified registries must correct any deficiencies or data errors identified through targeted audits prior to the submission of data for that MIPS payment year. In addition, we would like to remind the commenter that third party intermediaries must certify that all data submitted to CMS by the third party intermediary is true, accurate, and complete to the best of their knowledge. This certification applies to all data the third party intermediary submits to CMS on behalf of a MIPS eligible clinician, group or virtual group, and does not exclude data exports directly from an EHR or other data sources. You may refer to the 2021 QCDR and Qualified Registry self-nomination fact sheets for additional information. These resources are available at *https://qpp.cms.gov/about/resource-library.*

Comment: One commenter noted that the auditing of Improvement Activities has been and will continue to be a source of validation difficulty during auditing. The commenter also noted because improvement activities are not necessarily tracked within the EHR and that these items often consist of narrative information recorded and tracked elsewhere by the provider, they

should not be considered an auditable item for the third party intermediary. One commenter requested that if these requirements are finalized in the future, CMS provide discrete data points for improvement activities that do not require collection of data points.

Response: We disagree that data regarding improvement activities should be excluded from the data validation and audit requirements for QCDRs and qualified registries. We appreciate the commenter's concern that some current clinicians and groups may have current practices for documenting and tracking improvement activities that may make validating this information more challenging. However, we do not believe these operational concerns should result in improvement activities being excluded from data validation and targeted audit requirements. Within the data validation and targeted audit requirements, QCDRs and qualified registries must submit to CMS the results of each data validation audit and targeted audit, including, among other information, how and when each deficiency or data error type was corrected. In addition, QCDRs and qualified registries must correct any deficiencies or data errors identified through targeted audits prior to the submission of data for that MIPS payment year. Regarding discrete data points for improvement activities, we interpret the commenter to be requesting future guidance on how to validate improvement activities if the activity does not require collection of data. However, we clarify that completion of each improvement activity involves some form of underlying documentation, for example, in order to complete the CDC training for IA_PSPA_23—Completion of CDC Training on Antibiotic Stewardship the module requires the MIPS eligible clinician to receive a certificate of completion and per the MIPS Data Validation Criteria document would be required to maintain this certificate for a period of up to 6 years in the event of a CMS audit. Therefore, we believe it is reasonable to require data validation for improvement activities.

Comment: A few commenters stated that while a QCDR can support eligibility verification, CMS should support this process by creating scalable and secure access to this information by either pulling data for QCDRs or having an application programming interface that communicates such information. One commenter also requested that CMS include language in the final rule emphasizing that eligibility verification is ultimately the clinician's responsibility, and not the QCDR's.

Response: As the submitter of data on behalf of the clinicians, we believe QCDR should check on clinician eligibility so that the clinician can make an informed decision regarding participation.

While we understand the commenters' recommendation may relieve some burden on the QCDRs from verifying eligibility, it is not operationally feasible to depend on CMS to conduct this verification on behalf of the QCDRs. QCDRs should verify and track the eligibility of the clinicians and groups they intend to support for purposes of MIPS reporting. This becomes particularly important for tracking purposes, in case issues arise with regard to final scores and payment adjustments, as it is necessary for the QCDR to delineate MIPS eligible clinicians from voluntary participants and opt-ins.

We provide the public, including QCDRs participating in the Quality Payment Program, with an Application Programming Interface (API) that can assist with determining eligibility for clinicians and groups which can be found at *https://cmsgov.github.io/qpp-eligibility-docs/*. Information can be obtained primarily by the Clinician type, by searching by NPI. The information contained in these endpoints includes basic enrollment information, associated organizations, information about those organizations, individual and group special status information.

Comment: One commenter stated that verifying the accuracy of TINs and NPIs is burdensome for some QCDRs and requested that CMS provide clarification regarding this verification as well as allow flexibility in how such data are verified.

Response: We continue to receive data that cannot be attributed to a specific clinician due to an inaccurate TIN, NPI, or TIN/NPI combination. While we understand there is a level of effort on the part of the QCDR that is required to verify the accuracy of TINs and NPIs, we believe this is an important requirement for QCDRs to track. We have provided suggested methods in the CY 2017 Quality Payment Program final rule of verifying the accuracy of TINs and NPIs (81 FR 77366), but we have not required QCDRs to use this approach. Any alternative process used by the QCDR should be reliable, valid, and capable of being repeated in a manner that is consistent for all verification attempts.

Comment: One commenter requested confirmation as to how random human errors should be treated under the targeted data audit requirement when identified during the randomized audit process. Specifically, the commenter requested clarification on whether a targeted audit needs to be conducted on a separate sample universe (for example, on a sample that does not include any data from the sample used for the data validation audit in which the error was identified) if, for example, the only errors identified during the randomized audit were attributed to random human error, such as a human medical coding error. The commenter also requested for clarification on whether it is sufficient to document that a detailed review was conducted as part of the randomized audit process to identify the root cause of the error (for example, that the root cause was, in fact, attributable to random human error) and to establish and implement a plan for correcting any such random human errors that were identified.

Response: We reiterate for QCDRs all policies regarding data validation audit and targeted audit requirements at § 414.1400(b)(2)(iv) and (v) must be followed. All errors, regardless of whether they are human-based or systems-based must be identified as a part of the data validation efforts. If an error is identified through data validation, regardless of whether the error is human-based or systems-based, that would then trigger the QCDR to conduct a targeted audit utilizing a sample that is unique to the sample that was used for the data validation audit. It is not sufficient to document a detailed review or root cause analysis that was done as a part of the data validation audit (previously referred to as the randomized audit). We believe that QCDRs should utilize a structured data validation methodology, inclusive or a targeted audit in instances where the data validation audit results in the discovery of errors. An audit process provides a level of structure that will lead to consistency in the type of findings discovered. Furthermore, we are concerned with allowing QCDRs discretion to conduct their root cause analysis using an undefined variety of methods may lead to arbitrary and incomplete findings. The QCDR must separately conduct the targeted audit in accordance with regulatory requirements in each instance in which data validation audit identifies one or more deficiency or data error. An alternative approach to the targeted audit will not be accepted. We will maintain our structured validation process, in which the results of the audit are shared in a manner that is standardized across all participating QCDRs and qualified registries.

Comment: A few commenters stated that this requirement of data validation audits would create additional burden and operational challenges because QCDRs have no official role, delegated authority, or guidance from CMS as a CMS auditor. Commenters also stated that if a practice disagrees with the decision of a QCDR audit, there is no clear path as to how a QCDR could respond and be supported in their decision by CMS. One commenter also stated that CMS should allow Improvement Activities submissions that QCDRs receive be sent to CMS's QPP service center so that the service center can provide guidance to QCDRs on whether each submission can be accepted/approved.

Response: While we understand data validation requires a level of effort by the QCDR, we want to note the importance of QCDRs validating the data they intend to submit to us for purposes of the MIPS program. It is our expectation that QCDRs will ensure that the data submitted is true, accurate, and complete. To be clear, QCDRs are not designated to be auditors on behalf of CMS. QCDRs are required to conduct validation to promote the accuracy of their own submissions. We encourage the QCDR to keep documentation of instances in which a clinician does not provide the data requested for validation, and suggest that the QCDR consider annotating the report with the results of their data validation audits to outline instances where clinicians refuse to cooperate. The inclusion of information of these occurrences will help bring such issues to our attention, and may lead to the non-compliant clinician's selection for auditing as described in § 414.1390. While QCDRs are required to conduct data validation regardless of the clinician type and performance category; we clarify that clinicians who fail to submit accurate data to us, regardless of whether they use a third party intermediary or submits their data directly to us, will also be held responsible. We disagree that the QPP Service Center should be involved in determining data for an improvement activity are valid. QCDRs are expected to utilize the existing improvement activity guidance that may be found in the resource library at *www.qpp.cms.gov* to validate that the clinician or group has successfully completed the activity before it is attested to.

Comment: Many commenters disagreed with the proposal to require data validation specific to performance category, submission mechanism, and submitter type. Commenters believe the proposal is duplicative of internal quality data controls and external audits already conducted; and data validation for clients who are manually entering data may be difficult to audit, as many clinicians and practices do not complete data entry until late in the fourth quarter of the performance period.

Response: We disagree with the commenters objecting to the scope of data validation. As described in the CY 2021 PFS proposed rule (85 FR 50324), the data validation requirements including validation specific to performance category, submission mechanism, and submitter type align with current practices currently utilized by QCDRs that have been in place since the 2017 performance period of the MIPS program, and therefore, pose no additional burden. We acknowledge that QCDRs in previous years of the MIPS program have performed data validation audits utilizing internal resources or hiring external contractors and have been able to share the results of their data validation with CMS. By establishing these data validation requirements in regulation, it is our intent to ensure minimum validation efforts are robust and consist across all QCDRs. We understand that some clinicians and practices may not complete data entry until late in the fourth quarter of the performance period, but we disagree that should be a deterring reason as to why QCDRs could not validate data. We encourage QCDRs to advise their participants to submit data throughout the year. By receiving data earlier in the year, not only will the QCDR be able to validate their data earlier, but they will be able to provide more timely performance feedback to their clinicians and groups in accordance with § 414.1400(b)(2)(ii), which would allow the clinician to take action on the data and improve the quality of care their patients receive—which is one of the main goals of the program.

Comment: One commenter disagreed with the proposal to apply this requirement to voluntary submitters since they would be required to agree to the audit requirements and their incentive to participate may be hampered by the additional work associated with the audit.

Response: We appreciate the commenter's concern that data validation may be a disincentive to some voluntary submitters; however, we believe this concern is outweighed by the need to promote the accuracy of the data we receive. We want to note that all data submitted may be subjected to display on Physician Compare internet website of CMS (or a successor website), and that data would be subjected to the requirements at § 414.1395. Accordingly, all data submitted to us will face the data validation audit and targeted audit requirements at § 414.1400(b)(2)(iv) and (v).

Comment: Another commenter suggested CMS may consider having QCDRs prepared to provide such documentation upon request, as it does for other audits in order to minimize burden on behalf of the vendors, practices they contract with, and CMS, while upholding the integrity of these audits. One commenter stated that the requirement to use clinical documentation may not be feasible for all QCDRs to complete. The commenter stated the QCDR may not have access to the medical record because they do not always have business associate agreements (BAAs) set up that allow for data access, and that without this access to the medical charts, the data validation and audit will be unable to occur.

Response: As described at § 414.1400(g)(2), all third party intermediaries must retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period. However, these documentation retention requirements are distinct from the data validation requirements. To be clear, QCDRs should have access to clinician documentation in order to complete the data validation requirements, and the access should be readily provided by clinicians who are selected through the sampling methodology. It is not sufficient to merely have this documentation available upon CMS request in meeting these data validation and targeted audit requirements since the validation and auditing must be completed prior to data submission.

Comment: One commenter requested that CMS provide a template and/or guideline for the data validation process and report.

Response: On an annual basis, we have provided QCDRs with data validation execution report templates, so they could share information about their data validation process and results with CMS. We refer readers to the Quality Payment Program resource library website at *https://qpp.cms.gov/about/resource-library* where we have published these in the past. At § 414.1400(b)(2)(iv) and (v) we are finalizing regulatory requirements for annual reports to regarding data validation and targeting audits for the 2023 MIPS payment year and beyond. We intend to publish updated report templates in the QPP Resource Library: *https://qpp.cms.gov/about/resource-library*.

Comment: One commenter requested that CMS publish minimum data accuracy requirements due to its belief that performance data is never 100 percent accurate and since QCDRs do all that is within their power to ensure data accuracy, they should not incur fines or other disciplinary action for data accuracy issues outside their control.

Response: Ensuring data is correct and suppressing inaccurate data is the responsibility of the QCDR. Accurate data is critical to calculate any payment differentials for clinicians in addition to displaying performance results on one of our compare websites. It is anticipated that the accuracy of data should improve over time and thus setting a specific reliability threshold does not allow the flexibility needed to preclude poorly performing vendors.

Comment: A few commenters noted that in order to facilitate data validation, CMS should provide a mechanism to identify and verify the clinicians that are associated with a group by TIN and NPI. The commenters believed that QCDRs could more successfully serve clinicians if this information was readily available within the QPP Portal early in the performance year rather than requiring QCDRs to access the CMS Developer or Submissions API, which is not available until the third or fourth quarter of a reporting year.

Response: For the provider eligibility, CMS provides the public, including QCDRs participating in the Quality Payment Program, with API that can assist with determining eligibility for clinicians and groups which can be found at *https://cmsgov.github.io/qpp-eligibility-docs/.* Information can be obtained primarily by the Clinician type. You can query the Clinician type by passing in an National Provider Identifier, or NPI. The information contained in these endpoints includes basic enrollment information, associated organizations, information about those organizations, individual and group special status information. QCDRs do have access to the public API. The API is updated when our eligibility data is updated for the public. Therefore, QCDRs have the availability to pull the data at the same time as clinicians to go into the QPP look up tool to check their eligibility. The final eligibility runs are not complete until the second eligibility determination period concludes, which falls on the close of the Fiscal Year. We do not allow TIN lookup, as this information is viewed as PII, but all data can be viewed by group name or NPI. In addition, we do offer third party intermediaries, excluding the CAHPS for MIPS vendors, the ability to utilize OAUTH integration to allow for more robust set of access and integration. Please refer to sections VII. and VIII. of this final rule where this process is discussed in greater detail.

After consideration of public comments, we are finalizing the proposed data validation requirements and targeted audit requirements at § 414.1400(b)(2)(iv) and (v) as proposed.

(b) QCDR Measures

We refer readers to § 414.1400(b), the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), and the May 8th COVID–19 IFC (85 FR 27594 through 27595) for where we previously finalized standards and criteria for QCDR measures. In the CY 2021 PFS proposed rule (85 FR 50326), we proposed modifications to previously finalized QCDR measure requirements. While we understand the level of time and work needed to meet these requirements, we would not be grandfathering in previously approved QCDR measures.

(i) QCDR Measure Considerations and Requirements for Approval or Rejection

We refer readers to § 414.1400(b)(3), the CY 2020 PFS final rule (84 FR 63059 through 63073) for our previously finalized policies related to the QCDR measure considerations and requirements for approval or rejection. Through education and outreach, we have heard stakeholders' concerns about the complexity of reporting when there is a large inventory of QCDR measures to choose from, and we noted that we believe the proposals would help to refocus measures to those most meaningful to a clinician's scope of practice.

In the 2021 PFS proposed rule, we proposed to modify a few QCDR measure requirements: Measures in MVPs; measure testing; duplicative QCDR measures; and collection of data as discussed below.

(A) QCDR Measures in MVPs

We refer readers to section IV.A.3.a. of this final rule, where we discuss QCDR measures in MVPs. While we acknowledged the level of innovation that QCDRs have put forward as they have developed and implemented QCDR measures, we noted the differences between the QCDR measures utilized in the existing MIPS reporting method versus that of MVP reporting. In the current MIPS program, clinicians and groups may select to report on measures from a large library of what is available through the MIPS quality measure inventory and that of the QCDR measures available, if they choose to report through a QCDR. In our gradual transition to MVPs, we move to subsets of measures and activities, where clinicians may have a more focused selection of items to report on.

For that reason, it is important that the measures included in an MVP are reliable, feasible, and valid as to not inadvertently cause a clinician or group an issue with submission, calculation, and scoring of a given measure. We refer readers to our discussion below about measure testing requirements for QCDR measures in MVPs.

(B) Measure Testing Requirements

In the CMS Blueprint,[142] measure testing enables a measure developer to assess the suitability of the quality measure's technical specifications and acquire empirical evidence to help assess the strengths and weaknesses of a measure with respect to the NQF Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. Information gathered through measure testing is part of full measure development, and this information can be used in conjunction with expert judgment to evaluate a measure. For Blueprint purposes, measure testing refers to testing quality measures, including the components of the quality measures, such as the data elements, the instruments, and the performance score.

We refer readers to the CY 2019 PFS final rule, where we gave notice to the public that we were considering proposing to require reliability and feasibility testing as an added criterion for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). After consideration of the previous public comments received, and our priority to ensure that all measures available in MIPS are reliable and valid thereby reducing reporting burden on eligible clinicians and groups, we finalized a requirement to require all QCDR measures to be fully developed and tested, with complete testing results at the clinician level, beginning with the CY 2023 payment year in the CY 2020 PFS final rule (84 FR 40816).

(aa) Measure Testing Requirements in IFC

In response to the PHE, we issued changes in the May 8th COVID–19 IFC

[142] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

(85 FR 27594 through 27595). We had heard from third party intermediaries, specifically QCDRs, that due to the COVID–19 pandemic they anticipated being unable to complete QCDR measure testing or collect data on QCDR measures for the 2021 MIPS performance period as specified at § 414.1400(b)(3)(v)(C) and (D). Both QCDR measure approval criteria necessitate QCDRs collecting data from clinicians in order to assess the measure. Over 50 percent of the QCDRs approved for the 2020 performance period are supported by specialty societies that represent and support clinicians on the front lines of the COVID–19 pandemic, or are hospitals that are directly impacted by the pandemic. We also anticipated that there will be a lack of available data for some QCDR measures because clinicians who work in specialties that are not primarily caring for COVID–19 patients may have their cases or elective procedures canceled or delayed so that resources can be redistributed. As a result, we anticipated that QCDRs may be unable to collect, and clinicians unable to submit, data on QCDR measures due to prioritizing the care of COVID–19 patients.

We believed that clinicians who are on the frontlines taking care of COVID–19 cases should not be burdened with having to submit data to a QCDR for purposes of QCDR measure assessment (testing and data collection). In consideration of clinicians' limited resources and in an effort to reduce burden on clinicians and health care organizations that are responding to the COVID–19 pandemic, we are amending the QCDR measure approval criteria previously finalized in the CY 2020 PFS final rule (84 FR 63065 through 63068), specifically the completion of QCDR measure testing at § 414.1400(b)(3)(v)(C) as discussed in section II.R.1. of the May 8th COVID–19 IFC (85 FR 27594 through 27595).

In the CY 2020 PFS final rule (84 FR 63065 through 63067), we finalized at § 414.1400(b)(3)(v)(C) that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. For the reasons discussed in May 8th COVID–19 IFC (85 FR 27594 through 27595), we delayed the implementation of this policy by 1 year. Specifically, we amended § 414.1400(b)(3)(v)(C) to state that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

During this 1 year delay, we will continue to review QDCR measures as in past years to ensure they are valid, reliable, and align with the goals of the Meaningful Measure initiative. This process includes review by quality measure experts; QCDR policy subject matter experts; clinicians, including physicians, nurses, and PTs/OTs, who work on our support contractor team; and CMS Medical Officers. We will continue to review QCDR measures for potential risk of patient harm (for example, QCDR measures that promote clinical practices related to overuse). We also will continue to review QCDR measures for feasibility and accuracy and reliability of results. For more information, we refer readers to the 2020 QCDR Measure Development Handbook.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed delay of QCDR measure data collection requirements such that developers will have until the 2022 performance period to collect complete testing results at the clinician level prior to submitting new measures for consideration.

Response: We thank commenters for their support.

Comment: One commenter recommended that CMS gradually implement the requirements and continue to monitor the impact COVID–19 may have on QCDR testing. The commenter expressed concern that it can take a developer months to execute a QCDR testing contract with a testing vendor and that the current number of vendors available will not be able to meet the increased demand. The commenter recommended that CMS allow a grace period for the new requirements for existing measures, with an initial focus on testing measures reported by the majority of QCDR participants. For new or modified measures, the commenter recommended that CMS provide provisional approval and require testing in a future year when more data is available for testing.

Response: We refer readers to the CY 2018 Quality Payment Program proposed rule (82 FR 30160) where we described our goal and sought comment on having fully tested QCDR measures within the MIPS program. Furthermore in the CY 2019 PFS final rule, we gave notice to the public that we were considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). Furthermore, as we have signaled through previous rulemaking cycles (83 FR 59901 through 59902), we have intended to raise the bar for QCDR measures that are available for reporting within the MIPS program.

After consideration of the public comments received in the CY 2019 PFS final rule, and our priority to ensure that all measures available in MIPS are reliable and valid thereby reducing reporting burden on eligible clinicians and groups, we moved forward with our proposal in the CY 2020 PFS proposed rule. Consequently, in the CY 2020 PFS final rule (84 FR 63065 through 63067), we finalized at § 414.1400(b)(3)(v)(C) that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. For the reasons discussed in May 8th COVID–19 IFC (85 FR 27594 through 27595), we delayed the implementation of this policy by 1 year, until the 2022 performance period. Even before the publication of the May 8th COVID–19 IFC, QCDRs should have already been preparing for this measure testing to occur as part of the finalized policies in the CY 2020 PFS final rule. We believe stakeholders have had adequate notice of this requirement in order to prepare. Furthermore, as described in section IV.A.3.g.(2)(b)(i)(B) of this final rule, we are finalizing the proposed updates to the QCDR measure testing requirement to implement the measure testing requirement in an incremental manner.

Based off experience in past performance periods of the MIPS program, there have been several situations where QCDRs have flagged for us mid performance period that they had issues collecting data on a QCDR measure, had trouble implementing the QCDR measure, or had technical issues with the measure specifications. These issues, identified mid performance period have led to QCDRs informing us that they could no longer successfully support the reporting of the impacted QCDR measure. Such issues have had downstream impacts on clinicians who have to scramble at the last minute to quickly find an alternative measure to report to satisfy the quality reporting requirements of the MIPS program. It is evident that such issues demonstrated that these measures lacked reliability, validity, and feasibility and should not have been utilized in the program. Therefore, we believe it is critical to implement measure-testing standards

that will ensure that the QCDR measures in the MIPS program are reliable, valid, and feasible. This requirement will avoid the inadvertent burden to clinicians, particularly small practices and rural practices, that is associated with issues that occur with QCDR measure during the performance period. We understand that it is difficult to determine how the PHE for COVID–19 will impact QCDRs, but believe it is imperative that QCDR measures that are available in the program are reliable because of the associated scoring calculations that are connected to payment adjustments in the MIPS program. Furthermore, as described in the CY 2020 PFS final rule (84 FR 63066), while we understand the increased time and cost burdens associated with measure testing, we believe the benefits of completed measure testing far outweigh the burdens of it. We want all measures available in the MIPS program to be reliable, feasible, valid, and implementable within the program. We want to avoid scenarios that would arise by allowing measures that do not meet these standards, which then may lead to issues with the measure mid performance period. We do not believe it is appropriate to have untested measures within the MIPS program since clinician's performance on measures have impacts on their payments. We acknowledge that not all QCDR measures currently approved would continue in the program due to business decisions by each QCDR.

After consideration of public comments, in this final rule we are finalizing the delay of this policy by 1 year, such that § 414.1400(b)(3)(v)(C) states that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. To clarify, this policy is effective from May 8, 2020 through the end of the MIPS 2022 performance period since we are finalizing further changes to this policy below as described in section A.3.g.(2)(b)(i)(B) of this final rule, where we discuss the finalization of the proposed updates to the QCDR measure testing requirement to implement the measure testing requirement in an incremental manner beginning with the 2022 performance period.

(bb) Overview

With this delay in mind and based on stakeholder feedback on the level of burden, the limited amount of time, and costs associated with measure testing after the CY 2020 PFS final rule published, in the 2021 PFS proposed rule, we proposed to both further modify our QCDR measure testing policy generally and add testing policies for QCDR measures that are being considered for inclusion in MVPs. In that rule, we noted that we continue to believe that reliable, valid measures with robust testing with empirical data should be used in quality evaluation and payment programs. However, we discussed that we want to balance those interests with stakeholders' concerns. Therefore, we proposed a gradual approach to have fully tested QCDR measures within the MIPS program. We emphasized that we still believe that all QCDR measures should be fully tested, particularly as we rely on the data from these measures to score clinicians which impact their final score and associated MIPS payment adjustments, and as we seek to utilize QCDR measures in MVPs, as summarized in section IV.A.3.a of this final rule. In the 2021 PFS proposed rule, we proposed at § 414.1400(b)(3)(v)(C)(*1*) that, generally, to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. Therefore, we proposed to revise § 414.1400(b)(3)(v)(C) to account for an incremental approach to require fully tested QCDR measures. We discussed requirements for QCDR measures considered for inclusion in an MVP separately. These policies are discussed in more detail further below.

(cc) Requirements for Existing QCDR Measures

In the 2021 PFS proposed rule, we proposed that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. Face validity is defined in the CMS Measures Blueprint [143] as the following: The extent to which a test appears to cover the concept it purports to measure ''at face value.'' It is a subjective assessment by experts of whether the measure reflects the quality of care (for example, the utilization of a current clinical guideline to frame the measure, such as using the blood pressure guideline of < 140/90 is a marker of quality).

In addition, we proposed that these measures, which were approved for the preceding MIPS performance year with face validity (that is, CY 2024 MIPS payment year), would be required to be fully tested prior to being self-nominated for any subsequent performance periods (that is, CY 2025 MIPS payment year and beyond) in order to be considered for inclusion in the MIPS program.

In the CY 2019 PFS final rule, we referred readers to the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*) for a definition of ''fully developed with completed testing results at the clinician level'' (84 FR 40817). Our Blueprint discusses both alpha and beta testing (Blueprint 15.0 September 2019 Page 207–208). To avoid any potential confusion, we clarified in the CY 2021 PFS proposed rule that for purposes of QCDR measures, we would expect QCDR measures to complete beta testing to be considered fully tested. Beta testing is defined in the CMS Measures Blueprint [144] as the following: Beta testing (that is, field testing) generally occurs after initial technical specifications have been developed and is usually larger in scope than alpha testing. In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure. For example, beta testing allows for an enhanced evaluation of a measure's importance, including evaluation of performance thresholds, disparities analysis, and outcome variation. It helps in looking for opportunities for improvement in the population, which aids in measuring the QCDR measure's importance for reasons that include evidence collection to measure variability among comparison groups, to demonstrate the measure is not topped-out where most groups achieve similarly high performance levels approaching the measure's maximum possible value. We referred readers to the CMS Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/*

[143] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[144] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

Blueprint.pdf for additional details regarding beta testing.

The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to delay the requirement for QCDR measures to be fully tested by 1 year and only require face validity for the 2021 performance period.

Response: We thank commenters for their support. In the 2021 PFS proposed rule, we proposed that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. We want to clarify for commenters that this policy would affect the 2022 performance year.

Comment: A few commenters recommended that the requirement for full measure testing should be further delayed until at least 1 year after the PHE for COVID–19 ends. One commenter cited its preference for an approach where a potential measure is tested and peer reviewed by a committee for inclusion in the program.

Response: In the May 8th COVID–19 IFC (85 FR 27594 through 27595), we already delayed the requirement due to the PHE, such that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. However, in the 2021 PFS proposed rule, we proposed further changes, such that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. In addition, we proposed that these measures, which were approved for the preceding MIPS performance year with face validity (that is, CY 2024 MIPS payment year), would be required to be fully tested prior to being self-nominated for any subsequent performance periods (that is, CY 2025 MIPS payment year and beyond) in order to be considered for inclusion in the MIPS program. Therefore, fully tested measures are not required until the CY 2025 payment year and subsequent years (CY 2023 performance year). We believe this is a reasonable amount of time to prepare and balances the need to have fully tested, valid, and reliable measures in the MIPS program, which bases payment on quality metrics such as QCDR measures. While we do not specifically require QCDRs to utilize a process that involves peer review by a committee, we support those QCDRs that wish to do so.

Comment: A few commenters requested additional clarification on the required process and evaluation criteria for QCDR measure testing. Commenters requested detailed requirements and specific targets to enable greater understanding of how testing should be completed, as well as clarification on how CMS will evaluate the measures to determine if they ''pass'' and whether full measure testing will undergo the same, similar, or a different rigor as the National Quality Forum's measure testing. Commenters also requested clarification on the likelihood of QCDRs having their measures accepted if they are not fully tested; how the level of testing affects the measure review process in the future; who is conducting the measure review process; and what format is being used. Other commenters suggested that CMS empanel specialty specific committees of knowledgeable clinicians to evaluate self-nominated quality measures and should a QCDR measure not be approved, CMS should provide specific information on what criteria were not met and enable the QCDR to correct the deficiencies in time for the measure reconsideration meeting. One commenter provided the following recommendations regarding QCDR measure testing requirements: When assessing face validity, CMS should allow for a clear and direct association with a clinical guideline to be sufficient to fulfill face validity for a measure, especially when the guidelines are released by organizations with a strong record of high-quality clinical guideline development; if a QCDR measure has been endorsed by the NQF and is submitted to CMS, the requirement to document measure testing information for CMS should be waived, as long as the NQF measure ID is provided; and once a thoroughly tested QCDR measure has been approved by CMS, the testing requirement should be waived for subsequent years unless CMS identifies a significant substantive change to the measure that would necessitate new testing.

Response: As discussed in the proposed rule and above, in the CY 2019 PFS final rule, we referred readers to the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*) for a definition of ''fully developed with completed testing results at the clinician level'' (84 FR 40817). Our Blueprint discusses both alpha and beta testing (Blueprint 15.0 September 2019 Page 207–208). To avoid any potential confusion, we clarified in the CY 2021 PFS proposed rule that for purposes of QCDR measures, we would expect QCDR measures to complete beta testing to be considered fully tested. Beta testing is defined in the CMS Measures Blueprint [145] as the following: Beta testing (that is, field testing) generally occurs after initial technical specifications have been developed and is usually larger in scope than alpha testing. In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure. For example, beta testing allows for an enhanced evaluation of a measure's importance, including evaluation of performance thresholds, disparities analysis, and outcome variation. It helps in looking for opportunities for improvement in the population, which aids in measuring the QCDR measure's importance for reasons that include evidence collection to measure variability among comparison groups, to demonstrate the measure is not topped-out where most groups achieve similarly high performance levels approaching the measure's maximum possible value. We referred readers to the CMS Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* for additional details regarding beta testing.

We understand the NQF's measure testing guidelines are described at *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx*. While our QCDR measure testing policies provide an incremental approach to measure testing while being available in the program, we believe our measure testing policies are similar. Thus, we anticipate that many measures that have received NQF endorsement would also be easily approved for this program; however, we are not waiving measure testing requirements. We note that QCDRs must self-nominate their measures each year unless the QCDR measure was approved for a 2-year period. We refer readers to the CY 2020 PFS final rule (84 FR 63073) where we discuss this process in more detail.

QCDR measures that do not meet the incremental requirements of measure testing over the 2-year period as described further above, will not be

[145] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

approved for use in the program for not meeting requirements. If a QCDR measure is not fully tested by the self-nomination period, the QCDR should delay self-nomination of the QCDR measure until a future year once it has been fully tested.

Comment: Several commenters disagreed with the requirement for QCDR measures to be fully tested. Commenters expressed concerns that validity testing beyond face validity is not feasible for most quality measures and due to the time and expense involved may cause some registries to no longer invest in measure development and potentially leave the program. One commenter noted that full measure testing fails to account for the significant investments that QCDRs already make when developing measures to ensure the accuracy of their measures, including vetting by clinical subject matter experts and reliance on clinical practice guidelines, the medical literature, and preliminary data. A few commenters encouraged CMS to consider alternatives to the measure testing process such as opening the measures for public comment.

Response: We believe that measures should be reliable and valid with robust testing using empirical data prior to inclusion in a national pay-for-performance CMS program. Quality measurement should ensure measures are reliable, valid, and feasible, and this is supported by literature.[146] We disagree that validity testing beyond face validity is not feasible, since the quality measures available in the MIPS quality measure inventory are fully tested. We understand there is time, effort, and resources involved with measure testing but we believe that this must be a requirement in order to ensure we have reliable, valid, and feasible measures in a pay-for-performance program such as MIPS. We do not believe that an alternative approach such as face validity or public comment alone would meet the same rigor of validity. Furthermore, QCDRs should be held to the same standards of requirements as other measure developers. QCDRs should be developing measures utilizing measure development standards that are universally accepted by measure developers, inclusive of standardized testing procedures. The utilization of clinical experts, reliance on clinical guidelines, medical literature, and preliminary data are common practices amongst measure developers to ensure measures are developed in a relevant manner. However, these criteria that are used to develop a measure, do not replace the need for measure testing which goes beyond measure development and ensures the measure is reliable, valid, and feasible.

After consideration of public comments, we are finalizing our proposals as proposed.

(dd) Requirements for New QCDR Measures

We proposed that for a new QCDR measure to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid; to be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

For example, for the CY 2026 MIPS payment year (the 2024 performance period), the self-nomination application period would open on July 1, 2023 and close on September 1, 2023. A QCDR that self-nominates a new QCDR measure by September 1, 2023 would need to complete face validity measure testing prior to submission in order for the measure to be considered for the CY 2026 MIPS payment year. If that new QCDR measure is approved for the CY 2026 MIPS payment year, it would need to be fully tested by the next self-nomination date for the CY 2027 MIPS payment year (by no later than September 1, 2024 for the 2025 performance period). QCDR measures that are not fully tested by the second year of the measure's life in MIPS (that is, second self-nomination date), would not be considered for approval for the second year.

We recognized that not all QCDR measures currently approved would continue in the program due to business decisions by each QCDR. We acknowledged that there is a cost involved with full testing of quality measures (see 84 FR 63173); however, we noted that we believe it is important that all measures used within the MIPS program are fully tested and reliable. We also noted that we believe this incremental approach in testing would allow QCDRs time to plan appropriately to complete measure testing in a timely, efficient, and effective manner. However, we encouraged QCDRs to submit fully-tested QCDR measures to the extent possible, as we have a strong preference for QCDR measures that are fully tested versus those that have only completed face validity testing.

The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposal to require new QCDR measures to be face valid for the 2024 MIPS payment year and to be approved for the 2025 MIPS payment year and future years. A few commenters also agreed that a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

Response: We thank the commenters for their support.

Comment: Several commenters disagreed with the requirement that new QCDR measures must be fully tested by the subsequent performance period after initial approval due to their belief that the requirement is costly, burdensome, and arduous. A few commenters further stated that QCDR measures are created by subject matter experts; undergo significant expert vetting; are supported by literature, guidelines, and preliminary data, providing rigorous face validity for each measure; and QCDRs typically review performance data before and after implementing a measure in the registry. One commenter stated that these requirements may lead to the costs of measure development outweighing the benefit of operating QCDRs and that CMS is inherently making it impossible for small organizations to run QCDRs and develop new measures.

Response: We disagree with the commenters. While we understand the level of effort, time, and finances involved with measure testing, we believe it is important that all measures in a national pay-for-performance program such as MIPS are fully tested, as they are relied upon to make performance determinations and thereby corresponding payment adjustments. CMS is holding measures used in the QPP program to the same standards—whether they be measures generally available or measures solely submitted by QCDRs. We do acknowledge and appreciate the efforts and participation of QCDRs that are run by organizations of varying sizes, but believe it is important to hold all measures to the same standard, to ensure that we have reliable, valid, and feasible measures in the MIPS program for clinician use. We understand that measure testing requires a level of effort, resources, finances, and time in order to be completed. However, we believe that all measures should meet such rigorous standards in a pay-for-performance quality reporting program. QCDRs that require more time to test their measures,

[146] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

may do so outside of the MIPS program, and can delay self-nominating a QCDR measure until the testing is appropriately completed.

Comment: A few commenters requested that CMS modify the proposed requirement that testing data for new QCDR measures must be submitted by the next self-nomination period and change it to the second self-nomination period due to its belief that many QCDRs rely on prospective data collection to generate the data needed for testing and therefore, will not have 12 months of data available and analyzed by the next self-nomination deadline (September 1). Another commenter stated that it would be impossible to explore and develop testing options and complete the testing process by the September 1, 2020 self-nomination deadline for the 2021 performance period.

Response: We refer readers to the CY 2020 PFS final rule (84 FR 63065 through 63067 and § 414.1400(b)(3)(v)(C), where we first finalized a requirement to fully test measures beginning with the 2022 performance period. Due to the PHE, we delayed this requirement in the May 8th COVID–19 IFC (85 FR 27594 through 27595), such that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. In this final rule, we are further changing our requirements to finalize that for a new QCDR measure to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid; to be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. We believe stakeholders have had adequate advanced notice of this requirement. This incremental approach in testing would allow QCDRs time to plan appropriately to complete measure testing in a timely, efficient, and effective manner. While we understand the level of effort, time, and finances involved with measure testing, we believe it is important that all measures in a pay-for-performance quality program such as MIPS are fully tested, as they are relied upon to make performance determinations and thereby corresponding payment adjustments.

After consideration of public comments, we are finalizing our proposal as proposed.

(ee) Requirements for QCDR Measures Considered for MVP

As an additional layer, we proposed at § 414.1400(b)(3)(v)(C)(*2*) that in order for a QCDR measure to be considered for inclusion in an MVP for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested. We noted that we believe it is imperative to ensure that QCDR measures are fully tested before being included in an MVP. Unlike traditional MIPS, where clinicians and groups may choose from a large inventory of measures to report on for purposes of the quality performance category, the MVPs seek to create a focused selection of measures and activities relevant to a specific clinical topic. Since clinicians and groups who choose to report on MVPs will be reporting on a subset of measures and activities, there will be heavy reliance on the QCDR measures being reliable, valid, and feasible for reporting purposes. For a detailed discussion of MVPs, we refer readers to section IV.A.3.a. of this final rule.

The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to require that QCDR measures that will be included in an MVP be fully tested.

Response: We thank commenters for their support.

Comment: One commenter stated that QCDR measures that are only undergoing testing should be considered for inclusion in MVPs and that Improvement Activity credit be given to practices involved in measure testing.

Response: We disagree that measures in the testing phase should be considered for MVPs; inclusion should be limited to only those that are fully tested due to this being a pay-for-performance national program. With regards to improvement activity credit, we would encourage stakeholders to submit recommendations for improvement activities during the Call for Improvement Activities that occurs on an annual basis for consideration and potential inclusion in the program for future years.

Comment: One commenter requested that CMS further delay full testing of QCDR measures and subsequently QCDR MVPs. A few commenters disagreed with the proposal to require QCDR measures to be fully tested at the clinician level prior to being considered for inclusion in an MVP due to the expense. The commenters also believe that it is inconsistent with the proposed timeline for QCDR measures under MIPS which requires face validity for performance year 2022 and full testing for performance year 2023.

Response: We disagree with commenters. We believe that in order for QCDR measures to be considered reliable metrics in a pay-for-performance program such as MIPS, the measures must be fully tested. Any delay in fully tested QCDR measures will have downstream impacts with regards to the timing in which these measures can be considered for inclusion in MVPs in future years. We also want to clarify that QCDR measures that were fully tested at the time of self-nomination (July 1, 2020 through September 1, 2020) for the 2021 performance period, would be eligible for inclusion in MVPs for the 2022 performance period. We are aware that full testing of QCDR measures was not a requirement for the 2021 performance period, but have come across instances where some QCDRs have been diligently working to test or have completed testing their QCDR measures that are currently in the program and believe those fully tested QCDR measures are potentially ready to be considered for inclusion within an MVP. QCDR measures that are not fully tested will not be considered for inclusion in an MVP.

After consideration of public comments, we are finalizing our proposal as proposed.

(C) Duplicative QCDR Measures

Throughout previous rulemaking cycles, we have communicated our desire to eliminate duplicative QCDR measures in the MIPS program, as it is counterintuitive to the Meaningful Measure Initiative (84 FR 63068). One of the methods we previously suggested to address duplicative measures is measure harmonization, as discussed in the CY 2020 PFS final rule (84 FR 63068 through 63070). We have received comments and questions from stakeholders, requesting clarification for us to define what we mean by measure harmonization.

In this rule, we intend on clarifying that measure harmonization means ''measures for which previously identified areas of duplication with other approved QCDR measures or MIPS quality measures have been addressed.'' We proposed to revise previously codified policies that refer to measure harmonization with this updated terminology.

Therefore, we proposed to revise § 414.1400(b)(3)(v)(E), to state, beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs

address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

In addition, we proposed to revise § 414.1400(b)(3)(vi) to state, beginning with the 2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

Furthermore, we proposed to remove two previously codified policies that we have identified as areas of redundancy. We proposed to remove § 414.1400(b)(3)(vii)(H), which states whether the previously identified areas of duplication have been addressed as requested, and to remove § 414.1400(b)(3)(vii)(L), which states whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality actions, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization. We noted that we believe the previously finalized regulatory text under § 414.1400(b)(3)(vii)(A), which states QCDR measures that are duplicative, or identical to other QCDR measures or MIPS quality measures currently in the program will address instances where areas of duplication amongst QCDR measures are not addressed or where a QCDR measure approved for a previous year is duplicative with a QCDR measure approved for the current year.

As a result of the proposed removals of two previously codified policies, we proposed technical updates to re-number the regulation text to reflect the removals. Therefore, in § 414.1400, we proposed to redesignate paragraphs (b)(3)(vii)(I), (J), (K), (M), and (N) as paragraphs (b)(3)(vii)(H), (I), (J), (K), and (L), respectively.

The following is a summary of the comments we received and our responses.

Comment: One commenter expressed its support for removing QCDR measures that reflect outdated clinical guidelines or if the QCDR that nominated the measure is no longer in good standing. A few commenters agreed with CMS' proposals to revise QCDR measure harmonization policies and remove previously codified policies that it has identified as redundant due to its belief that it supports standardization of measures across providers and settings.

Response: We agree that measures that reflect outdated clinical guidelines no longer provide accurate clinical measurement that can lead to quality improvement. In addition, we agree with commenters that a QCDR's standing in the program should impact the availability of their QCDR measures in the program. Furthermore, we thank commenters for agreeing with some of the criteria we use to retire measures from the program as well as our need to harmonize measures and the benefit it conveys to the program. Some of these benefits include fewer measures for clinicians to have to read through (burden reduction) as well as better direct comparison between providers reporting on the same measure as opposed to a similar measure.

Comment: One commenter encouraged CMS to continue to encourage measure development programs to identify commonalities and gaps in existing systems rather than create new programs to identify new measures. Another commenter urged CMS to implement adequate safeguards to ensure that measure harmonization occurs only when it is clinically appropriate to do so.

Response: We continue to encourage QCDRs and measure developers to address measurement gaps identified in the MIPS program. To clarify, we are not creating new programs to identify new measures but are utilizing our existing processes to identify measurement gaps. On an annual basis, we publish our CMS Quality Measure Development Plan (MDP) and the MDP annual report. The MDP helps us build and improve quality measures clinicians can report under the MIPS program. The MDP includes environmental scans, gap analyses, and work with stakeholders. This report is published on an annual basis to help us get expert input about the measures we need, prioritize areas of measure development, evaluate existing quality measures, to meet our goal value-based measures to support the Quality Payment Program. We refer readers to the Quality Payment Program Measure Development website where we have published the 2020 MDP Annual Report at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.* We encourage QCDRs to utilize the MDP as they work through the measure development-planning phase to determine which identified gaps they would like to address through measure development.

With respect to safeguards, when measures are reviewed for areas of duplication, all of the similar measures are evaluated. We would encourage QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

Comment: One commenter disagreed with the policies to remove a QCDR measure before its second year for it being topped out or duplicative of a more robust measure.

Response: We continue to believe that duplicative QCDR measures should not be in the MIPS program, as that is contradictory to the Meaningful Measure Initiative. Including duplicative or topped-out measures in the program adds to burden without meaningfully improving care or quality.

Comment: A few commenters requested CMS consider certain priorities when identifying duplicative QCDR measures and encouraging harmonization, such as: Prioritizing the original measure until subsequent measures are proven to have surpassed it, prioritizing the more scientifically rigorous measure, and identifying the measure that best advances the goals of the program. One commenter also requested that CMS consider providing measure stewards specific reasons when new measures are identified as duplicative and provide an opportunity to improve or replace the existing measure.

Response: We continue to encourage QCDRs to work collaboratively amongst each other to address areas of duplication within their QCDR measures. In this final rule, we are finalizing at § 414.1400(b)(3)(v)(E) that beginning with the 2022 MIPS payment year, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, we will not approve the duplicative QCDR measure. In our review of measures, we do try to identify new measures that might be duplicative and reasons why, inform QCDRs submitting duplicative measures, and encourage the QCDRs to address the duplication in a timely manner.

After consideration of the public comments, we are finalizing our proposals as proposed.

(D) Collection of Data on QCDR Measure

In the CY 2020 PFS final rule (84 FR 63067 through 63068), we finalized at § 414.1400(b)(3)(v)(D) that beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(i) Delay of Data Collection in IFC

As mentioned previously in this section of the final rule, due to the PHE we delayed certain requirements in the May 8th COVID–19 IFC (85 FR 27594 through 27595). In the CY 2020 PFS final rule (84 FR 63067 through 63068), we finalized at § 414.1400(b)(3)(v)(D) that beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. For the reasons discussed in section II.R.2. of the May 8th COVID–19 IFC (85 FR 27594 through 27595), we delayed the implementation of this policy by 1 year. Specifically, we amended § 414.1400(b)(3)(v)(D) to state that beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

During this 1-year delay, we will continue to review QDCR measures as in past years to ensure they are valid and identify performance gaps in the area of measurement. As described in the 2020 QCDR Measure Development Handbook, this process includes vetting the measures to ensure they are implementable and collectible, which includes an evaluation of the measure and coding constructs (for example, whether the measure is constructed as a ratio, proportional, or inverse measure). Additionally, we will review the evidence provided by the QCDR (for example, clinical studies and/or scientific journals) that would support the need for measurement in lieu of insufficient data collection to demonstrate that there is a measurement gap.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported the delay of QCDR data collection requirements on count of concerns due to burden and likely delays in the development of new measures, problems that would only be exacerbated by the current PHE for COVID–19. Another commenter urged CMS to continue to monitor the PHE for the viability of this requirement for CY 2021.

Response: We thank commenters for their support. We are continuing to monitor the PHE.

After consideration of public comments, we are adopting our policy as finalized in the May 8th COVID–19 IFC (85 FR 27594 through 27595).

(3) Qualified Registries

We refer readers to §§ 414.1305 and 414.1400, the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818), CY 2019 PFS final rule proposed rule (83 FR 59906), and the CY 2020 PFS final rule (84 FR 40819 through 40820) for our previously finalized policies regarding qualified registries. In the CY 2021 PFS proposed rule (85 FR 50328), we proposed a technical update to the title at § 414.1400(c) to rename it from ''qualified registry approval criteria'' to ''qualified registries'', to better align the title with the content of the regulation. In addition, we proposed requirements related to data validation audits and targeted audits.

In the CY 2017 Quality Payment Program final rule, we discussed our expectation related to QCDRs and qualified registries would conduct validation on the data they intend on submitting for the MIPS performance period (81 FR 77384 through 77386) and provide the results of the data validation to CMS in the form of a data validation execution report by May 31st of the year following the performance period. Our intention was to establish our expectation that qualified registries would establish a process to assess whether the data are true, accurate, and complete prior to submitting them to CMS for purposes of the MIPS program. We believe it is important to establish a requirement that qualified registries conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. In instances where a qualified registry discovers data are inaccurate or incomplete, the entity must correct the issue prior to submitting the data to CMS in order to provide accurate certification in accordance with § 414.1400(a)(5). A qualified registry that submits a false certification submits data that is inaccurate, unusable or otherwise compromised to CMS for purposes of the MIPS program may be subject to remedial action or termination under § 414.1400(f). We believe requiring qualified registries to validate the accuracy of the data they are submitting is an important safeguard to promote accurate payments under the MIPS program. Therefore, we proposed at § 414.1400(c)(2)(iii) and (iv) requirements beginning with the 2023 MIPS payment year as condition of approval each qualified registry must conduct annual data validation audits and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits. We also proposed specific obligations for those audits as discussed below.

- We proposed to codify at § 414.1400(c)(2)(iii)(A), the qualified registry must conduct their data validation audits prior to submitting any data to CMS for purposes of the MIPS program. We noted that we believe it is important for qualified registries to conduct validation audits to identify and fix concerns regarding data accuracy prior to submitting data to us, including potential issues related to data aggregation and calculation. Conducting the data validation prior to data submission will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete. In the CY 2017 Quality Payment Program final rule, we described this auditing using the term randomized audit (81 FR 77384). We proposed instead to refer to this audit as the data validation audit in an effort to be abundantly clear regarding our expectations that the qualified registry will purposefully construct a sample and conduct and audit that complies with specific regulatory requirements and also to distinguish these audits from the targeted audits discussed below and proposed at § 414.1400(c)(2)(v).
- We proposed to codify at § 414.1400(c)(2)(iii)(B), the qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories. We believe that it is important that data validation be done across all performance categories for which the qualified registry submits data since qualified registries must attest that data submitted to CMS is true, accurate, and complete and data for each of these performance categories can influence score calculation and payment adjustments.
- We proposed to codify at § 414.1400(c)(2)(iii)(C), that the

qualified registry must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants. We noted that we believe it is important for the data submitted to CMS be accurate for all clinicians and groups for which the qualified registry intends on submitting data to the MIPS program, regardless of whether they are required to participate, have opted in, or have chosen to voluntarily participate. Therefore, we proposed to require that the data validation audits should account for all types of submitters that are utilizing the qualified registry to submit data to CMS for purposes of the MIPS program. We noted the importance of validating data for all submitter types regardless of its use for payment or public reporting. Even clinicians who voluntarily report to MIPS and whose data are not used for payment purposes could have their data publically posted on the Physician Compare website. We noted that we believe all data the qualified registry submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.

• We proposed to codify at § 414.1400(c)(2)(iii)(D) that the qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. If the data a qualified registry intends to submit to CMS for purposes with the MIPS program are to demonstrate that a clinician did a particular clinical activity or achieved a particular clinical outcome, we noted that we believe meaningful validation of such data requires the qualified registry to use clinical documentation to confirm that the activity occurred or was performed.

• We proposed to codify at § 414.1400(c)(2)(iii)(E), the qualified registry shall conduct each data validation audit using a sampling methodology that meets the following requirements:

++ Uses a sample size of at least 3 percent of the TIN/NPIs for which the qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the qualified registry may use a sample size of 50 TIN/NPIs.

++ Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

We believe the aforementioned sampling methodology is appropriate for multiple reasons. First, the sampling methodology criteria are consistent with the methodology established under the legacy Physician Quality Reporting System (PQRS) program and as described in the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367). As this methodology has been used for many years under the legacy program, we believe stakeholders are well versed in executing data validation audits using this sampling methodology. Second, the proposed methodology accounts for QCDRs and qualified registries of varying sizes. Data validation requires a level of effort on the part of the qualified registry to execute a data validation plan, identify a sample, and collect information for purposes of chart review; therefore, we are cognizant that requiring a larger sample size would create additional burden on qualified registries and clinicians to account for a larger volume in TIN/NPIs and medical records for review.

• We proposed to codify at § 414.1400(c)(2)(iii)(F) that each qualified registry data validation audit must include the following:

++ Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant. We believe that it is important for the qualified registry to track the eligibility status of each clinician and group that wishes to use a third party intermediary to report, because accurate information regarding eligibility is important to ensuring payment adjustments are properly applied. Furthermore, verification of eligibility status is consistent with the requirement for qualified registries to track opt-in participants, as described at § 414.1400(a)(4)(iv) and in the context of clinicians who voluntarily report to MIPS helps ensure the accuracy of data publically posted on the Physician Compare website (or a successor website) of the CMS website.

++ Verification of the accuracy of Tax Identification Numbers (TINs) or National Provider Identifiers (NPIs). Correct TINs and NPIs are critical to ensure data submitted by the qualified registry are attributed to the correct clinicians and groups. Inaccurate NPIs or TINs may lead to inadvertent downstream impacts to the way clinicians and groups are scored, and assigned a payment adjustment.

++ Calculation of reporting and performance rates (for example, formulas included in the quality measure specifications). Qualified registries must follow the measure specifications when calculating reporting and performance rates. Calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure data are consistent, reliable, and have been calculated in a uniform manner.

++ Verification that only MIPS quality measures and qualified registry measures that are relevant to the performance period will be utilized for MIPS submission. Measure specifications for the MIPS quality measures and qualified registry measures go through maintenance on an annual basis. Use of outdated measure specifications would likely result in the qualified registry submitting inaccurate or compromised data for the clinicians and groups they support. While not all measures go through substantive changes on an annual basis, there are changes to codes that do occur annually that should be accounted for when programing measures. Therefore, we believe it is important that qualified registries are utilizing the most current version of the measure specification, relevant to the performance period in which they are participating.

• We proposed to codify at § 414.1400(c)(2)(iii)(G), that in a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. We believe it is important that the results of the data validation be shared with us in order for us to understand the types of issues the qualified registries have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education. It is our belief that the report will be largely comprised of issues that were identified and resolved. However, if an issue has been identified and could not be resolved, we would want to understand what the issue is and why it could not be resolved. We emphasized that all data submitted to CMS by a qualified registry on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge as described in

§ 414.1400(a)(5). If a qualified registry submits a false certification or data that are data that are inaccurate, unusable, or otherwise compromised, the qualified registry may be subject to remedial action or termination as described at § 414.1400(f).

• We proposed to codify at § 414.1400(c)(2)(iv)(A) that if a data validation audit under § 414.1400(c)(2)(iii) identifies one or more deficiency or data error, the qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year. We believe targeted audits are important to further evaluate the impact of deficiencies or data errors to the cohort of clinicians and groups that the qualified registry intends to submit data for, and for qualified registries to determine the reason the deficiency or data error occurred.

• We proposed to codify at § 414.1400(c)(2)(iv)(B), that the qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year. To promote the accuracy of the data submitted to the MIPS program for the payment year and to reduce the risk that the agency initiates payment calculations in reliance on inaccurate data, it is important for the qualified registry to conduct required targeted audits and correct any deficiencies and data errors identified through those audits prior to submitting the data to CMS.

• We proposed to codify at § 414.1400(c)(2)(iv)(C), the qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (c)(2)(iii)(E). The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified. We believe the sampling methodology we proposed for data validation audits is equally appropriate for the conduct of targeted audits. We believe that adopting the same methodology for both audit types would be less burdensome on qualified registries than requiring these entities to apply a separate sampling methodology for their targeted audits. Provided that data in the sample for the targeted audit does not overlap with the data that was reviewed in the data validation audit, we believe the targeted audit would provide the qualified registry with a reasonable perspective into impact and root cause of deficiencies and data errors across the data to be submitted without imposing the burden that would result from maintaining a separate sampling methodology for targeted audits.

• We proposed to codify at § 414.1400(c)(2)(iv)(D), in a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each error type was corrected. As is the case with the results of data validation audits, we believe it is important that the results of the targeted audits be shared with us in order for us to understand the types of issues the qualified registries have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education.

We requested comments on the proposals, including whether stakeholders are concerned with implementing the policies for the 2023 MIPS payment year, and if so, what barriers do they believe they would face in implementing the requirements.

The following is a summary of the comments we received and our responses. We also refer readers to the QCDR section of this final rule (section IV.A.3.g.(2)) where qualified registries can view applicable comments and responses.

Comment: A few commenters disagreed with the proposal to require qualified registries to conduct data validation due to their belief that it will unnecessarily increase burden for qualified registries who are already validating data prior to submission to CMS. One commenter disagreed with the requirement to perform data validation for each submitter type because of the low number of participants reporting via the qualified registry as individuals and stated that the randomized auditing on a small sample would result in the unintended consequence of increasing the burden of these clinicians without necessarily improving the quality of data submitted and that such a policy change would result in some practices being audited multiple times, sometimes within the same year, based on their submission category. Several commenters disagreed with the proposal to require data validation specific to performance category, submission mechanism, and submitter type due to their belief that the proposal creates unreasonable burdens for clinicians, qualified registries; would result in some individuals or groups being audited more often and less randomly in circumstances where the number of individuals/groups for a specific submitter type is lower; will impose a substantial financial burden on small, specialty society registries; is duplicative of internal quality data controls and external audits already conducted; and data validation for clients who are manually entering data may be difficult to audit, as many clinicians and practices do not complete data entry until late in the fourth quarter of the performance year.

Response: We continue to believe it is important to establish a requirement that qualified registries conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. Furthermore, at § 414.1400(c)(2)(iii) and (iv) requirements beginning with the 2023 MIPS payment year as condition of approval each qualified registry must conduct annual data validation audits and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits. We understand that some qualified registries may have a small number of clients that are submitting data through their registry for purposes of MIPS reporting, but believe that data integrity is a high priority, and believe that data validation should occur regardless of the size of the clinician population the third party intermediary supports. As a point of clarification, we do not require multiple data validation audits to occur within the same year. Our data validation sampling methodology allows qualified registries to select a percentage of their clients. As noted above, correct data is vital to inform clinicians of their quality performance—let alone determining payment differentials that affect all participants in the program.

Comment: Another commenter stated that while they can perform a randomized audit requesting documentation from the EHR on Promoting Interoperability measure data to ensure accurate transposition and monitoring of errors and clinical documentation to ensure the Improvement Activities was attested to correctly, any errors discovered will be errors on the part of the practice or physician, not the registry.

Response: We appreciate the commenter's observation that in some instances the data validation conducted by a qualified registry may identify errors that stem from inaccuracies in the data supplied by the practice or

physician. Data validation requirements are intended to help ensure the qualified registry's data submissions to CMS are true, accurate, and complete. Therefore, if a qualified registry identifies errors in data on a Promoting Interoperability measure or Improvement Activity that it attributes to a practice or physician, the registry has shared responsibility to ensure the registry's submissions to CMS do not include that inaccurate data.

After consideration of the comments received, we are finalizing our proposals as proposed.

(4) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548), CY 2019 PFS final rule (83 FR 59908 through 59910), and the CY 2020 PFS final rule (84 FR 63077 through 63080) for previously finalized policies for remedial action and termination of third party intermediaries.

As described in § 414.1400(f)(1)(i), the remedial actions CMS may take against a third party intermediary include requiring the third party intermediary to submit to CMS by a date specified by the agency a corrective action plan (CAP) to address the identified deficiencies or data issue, including that actions it will take to prevent the deficiencies or data issues from recurring. To clarify expectations and create consistency in the content of the CAPs provide by third party intermediaries, we proposed to revise and elaborate on the obligations for a CAP. Specifically, we proposed to modify § 414.1400(f)(1)(i) such that, unless different or additional information is specified by CMS, the CAP submitted by the third party intermediary must address four issues: (1) The issues that contributed to the non-compliance; (2) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (3) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not recur in the future and (4) the detailed timeline for achieving compliance with the applicable requirements.

We noted that we believe the four elements are generally warranted in each instance in which a CAP is required. First, any meaningful efforts at corrective action necessitate an understanding of what needs to be corrected. Therefore, we proposed at § 414.1400(f)(1)(i)(A) to require that each third party intermediary be required to articulate the issues that contributed to the non-compliance. The third party intermediary must articulate what factors cause it to fail in its obligation to meet program requirements. For example, a survey vendor subject to remedial action for not completing vendor trainings would be required to explain what factors lead to its failure to complete training. We noted that we believe this analysis will allow third party intermediary to improve their processes to better meet existing requirements and will allow CMS to better understand what operational and other challenges third party intermediaries face in meeting program requirements. Second, depending on the circumstances, non-compliance by a third party intermediary may affect an uncertain number of clinicians and groups and has the potential to implicate substantial program dollars. Accordingly, we proposed at § 414.1400(f)(1)(i)(B) to require that a third party intermediary subject to a CAP disclose to CMS the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program. We noted that we believe this information regarding the scope of harms is necessary for the agency to assess the full program impact of the non-compliance. Furthermore, we believe it is important for the CAP to include this impact information regardless of the clinician's participation status, because non-compliance may have programmatic implications even if it does not affect payment, such as for data posted on the Physician Compare website. Third, meaningful remedial action requires the identification of specific action steps both to address prior harm but to protect against future harms. Therefore, we proposed at § 414.1400(f)(1)(i)(C) that a third party intermediary subject to a CAP must address the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future. The third party intermediary will be expected to follow through with the implementation of the corrective actions and to see that the issue has been corrected permanently. It is important for us to understand in detail what actions the third party intermediary will take to resolve the issue and to evaluate the effectiveness of the proposed solution for long-term sustainability. Fourth, non-compliance must be resolved methodically and timely. Therefore, we proposed at § 414.1400(f)(1)(i)(D) that each CAP must include the detailed timeline for achieving compliance with the applicable requirements. We solicited public comments on the proposed revisions to our requirements for correction action plans.

We received one public comment on the remedial action and termination of third party intermediary proposals. The following is a summary of the comment we received and our response.

Comment: One commenter requested more information on the proposed new criteria for corrective action plans and how they would be quantified, particularly scope of clinician impact and/or harms.

Response: The new criteria in the regulation text at § 414.1400(f)(1)(i) clarify the content the CAPs provided by the third party intermediaries must include. The obligation for the CAP to identify impacts of the non-compliance on clinicians, groups and virtual groups establishes that the third party intermediary must supply information as to the volume and identity of clinicians, groups and virtual groups that are negatively impacted by the non-compliance of the third party intermediary. The appropriate method for quantifying impact will vary depending on the nature of the non-compliance. For example, if a third party intermediary submitted compromised data to CMS because it used a flawed TIN/NPI crosswalk, we would expect the CAP to include the total number and identifying information for the clinicians and groups whose data were inaccurate. The identification of impacts to clinicians would also helps us understand the volume of clinicians who may look to find a different method of reporting. Please refer to *qpp.cms.gov* for more information.

After consideration of the comment received, we are finalizing our proposal as proposed.

h. Public Reporting on Physician Compare

For previous discussions on the background of Physician Compare, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final

rule (84 FR 63080 through 63083), and the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

(1) Definitions & Proposed Regulation Text Changes

Physician Compare (*http://www.medicare.gov/physiciancompare*) draws its operating authority from section 10331(a)(1) of the Affordable Care Act, which defines the term ''Physician Compare'' to mean the internet website developed under this section of the statute. Physician Compare has continued to pursue a phased approach to public reporting under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. Section 104(f)(2) of the MACRA defines the term ''Physician Compare'' to mean the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website). To more completely and accurately reference the website for which CMS will post information available for public reporting, in accordance with section 104(f)(2) of the MACRA, we proposed to define Physician Compare at § 414.1305 to mean the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website). We sought comment on the proposal. For ease of reference, we use the term ''Physician Compare'' in this final rule.

We did not receive any public comments on defining the term ''Physician Compare'' to mean the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website). Therefore, we are finalizing the ''Physician Compare'' definition at § 414.1305 as proposed.

4. APM Incentive Payment

(a) Overview

Under the Quality Payment Program, Qualifying APM Participants (QPs) receive a 5 percent APM Incentive Payment in payment years 2019 through 2024. In the CY 2017 Quality Payment Program final rule (81 FR 77480 through 77489), we finalized at § 414.1450(d) that this payment is made based on the clinician's QP status in the QP Performance Period that is 2 years prior (for example, the 2021 payment will correspond to the 2019 performance year), and at § 414.1450(b)(1) that the payment is equal to 5 percent of the estimated aggregate payments for covered professional services in the base period (the year between the QP performance and payment years). We finalized at § 414.1450(c)(1) that the APM Incentive Payment amount is made to the TIN associated with the Advanced APM Entity through which an eligible clinician becomes a QP during the QP Performance Period. Under § 414.1450(c)(3), if an eligible clinician becomes a QP through participation in multiple Advanced APMs, CMS divides the APM Incentive Payment proportionally between the TINs associated with the QP's participation in each Advanced APM based on payments for covered professional services during the QP Performance Period. In addition, under § 414.1450(c)(2), we finalized that if the QP is no longer affiliated with the TIN associated with the QP's participation in the APM Entity, the APM Incentive Payment is made to the TIN listed on the QP's CMS–588 Electronic Funds Transfer (EFT) Application form.

In our first year making the APM Incentive Payment, we experienced operational limitations that made it difficult in certain cases to distribute the payment to a current billing organization associated with the QP according to the current regulations. In particular, we encountered challenges when QPs are no longer affiliated with the TIN associated with the QP's participation in the APM Entity through which they attained QP status, and when we were unable to make the APM Incentive Payment to the TIN listed on the eligible clinician's CMS–588 EFT Application form. In certain circumstances, it has been challenging to locate accurate billing organizations for some QPs 2 years after they earned QP status. For example, we have encountered situations such as inaccurate or missing billing associations for the QP because the QP has changed their primary billing TIN between the performance and the payment year, or the billing TIN through which the QP attained QP status is not the TIN through which CMS payments are processed, and so it is not possible for CMS to know that the two are in fact connected.

(b) APM Incentive Payment Amount

In the first Quality Payment Program final rule (81 FR 77480), we finalized at § 414.1450(b)(1) through (3) how we calculate the amount of the APM Incentive Payment. Specifically, we finalized that: (1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the incentive payment base period (that is, the calendar year immediately preceding the payment year); (2) the estimated aggregate payment amount for covered professional services includes all such payments to the QP (NPI) via any and all of their TIN/NPI combinations; and (3) in calculating the estimated aggregate payment for a QP, CMS uses claims submitted for covered professional services with dates of service from January 1 through December 31 of the incentive payment base period.

In the CY 2021 PFS proposed rule (85 FR 50332), we are clarifying that the APM Incentive Payment amount is calculated based on the paid amount of the applicable claims for covered professional services that are subsequently aggregated to calculate the estimated aggregate payments. We proposed to amend our regulation at § 414.1450(b)(1) to reflect that clarification.

Section 1833(z)(1)(A) of the Act specifies that the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3) of the Act. Because the APM Incentive Payment is a percentage of the estimated aggregate payments made, it would not be appropriate to calculate the APM Incentive Payment based on amounts that were allowed, but not actually paid by Medicare, for such covered professional services.

We also noted that, as provided in § 414.1450(b)(4) and (5), we exclude certain payments and adjustments, including the MIPS payment adjustments, when calculating the APM Incentive Payment amount.

We sought comment on the proposal. The following is a summary of the comments we received in response to our proposal regarding the amount of the APM Incentive Payment.

Comment: One commenter recommended CMS aggregate the APM Incentive Payment on the allowed amount instead of the paid amount and the difference should be retroactive. The commenter noted that calculating on the allowed amount would produce a higher bonus for eligible clinicians.

Response: We appreciate the commenter feedback, however, as noted in the proposed rule, such an approach would be inconsistent with the plain language of the statute which requires that the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3) of the Act.

Therefore, we are finalizing our proposal to amend the language at § 414.1450(b)(1) to clarify our use of paid amounts in calculating ''payments''.

(c) APM Incentive Payment Recipient

Under our current policy as finalized at § 414.1450(c), CMS first seeks to disburse the APM Incentive Payment to the TIN associated with the QP's participation with the APM Entity in the Advanced APM through which they earned QP status. If the QP is no longer affiliated with that TIN, we seek to disburse the APM Incentive Payment to the TIN listed on the eligible clinician's CMS–588 EFT form on the date that we make the payment. And if the eligible clinician becomes a QP through participation in multiple Advanced APMs, we seek to divide the APM Incentive Payment proportionally, based on payments for covered professional services during the QP Performance Period, and to make proportional payment to each of the TINs associated with the QP's participation with the APM Entity or APM Entities in the Advanced APMs.

It is still our intention to reward achievement of QP status through participation in Advanced APMs by seeking to disburse APM Incentive Payments to TINs that are affiliated with an APM Entity through which the QP has achieved QP status, as is described in the CY 2017 Quality Payment Program final rule (81 FR 77847). However, after our first year of making APM Incentive Payments, we have learned that the amount of time between when an eligible clinician earns QP status and when APM Incentive Payments are made makes it difficult to ensure that payments can be made for these QPs in a routine and efficient manner. For example, in the space of 2 years between making QP determinations and APM Incentive Payments, eligible clinicians may change TINs, join new TINs, join new APM Entities, remain in the same APM Entity under a new billing TIN, leave Medicare altogether, or make other potential changes impacting their relationship with the Medicare program. CMS receives updated records of the changes when APM participants update their payment information through the internet based Provider Enrollment, Chain and Ownership system (PECOS) or a CMS–588 EFT Application, and subsequent updates to APM Participation Lists and Affiliated Practitioner Lists, although we note that such updates are not consistently and timely made across APM participants, as we originally believed, and therefore such lists have variable reliability. Further, on our own end, if we limit our initial search for the party or parties to which we should make the APM Incentive Payment to only the TIN or TINs through which the eligible clinician earned QP status, as is specified in our regulations at § 414.1450(c)(1) and (3), when the QP has made changes to their TIN affiliations, we might limit our opportunities to make the APM Incentive Payment to a more current TIN with which the QP is affiliated at the time we make the APM Incentive Payment. If we limit the TINs to which we will make the APM Incentive Payment to only those through which a QP was billing at the time they achieved QP status, we might be unable to identify any TIN to which we would make a payment for that QP during the payment year, or payments may be significantly delayed as a result, even in cases where a current payee TIN is available.

Therefore, we proposed to establish in our regulation at § 414.1450(c) a revised approach to identifying the TIN(s) to which we make the APM Incentive Payment. We noted that this approach would involve looking at a QP's relationship with their TIN(s) over time, as well as considering the relationship the TIN(s) have with the APM Entity or Entities through which the eligible clinician earned QP status, or other APM Entities the QP may have joined in the interim. We stated that we believe that this revised approach will enable CMS accurately identify TINs with which QPs are currently receiving other Medicare payments, and through which they would likely anticipate receiving their APM Incentive Payment. We also noted that this approach would also prioritize, when the QP is no longer affiliated with the original TIN through which they achieved QP status, identifying and paying TINs with which QPs are affiliated at the time the APM Incentive Payment is made, thereby reducing the potential burden on payee TINs to find QPs no longer affiliated with them in order to disburse the APM Incentive Payment amount, as well as reducing uncertainty and delays for the QPs themselves as they anticipate their APM Incentive Payment.

We also proposed to introduce a cutoff date of November 1 of each payment year, or 60 days from the day on which we make the initial round of APM Incentive Payments, whichever is later, as a point in time after which CMS will no longer accept new helpdesk requests from QPs or their representatives who have not received their payments. We discussed that there may be scenarios where we are unable to identify any appropriate TIN to which the APM Incentive Payment should be made, such as when the QP is no longer participating in Medicare, the QP has recently reassigned his or her billing rights, or where a payment TIN may be undergoing business transformations such that payment information changes during the payment year. In these cases, it is our goal to make correct payments for the relevant QPs as soon as feasible. To do so, it is necessary to establish a date after which we will not consider additional inquiries or additional information from QPs or their representatives for purposes of disbursing remaining APM Incentive Payments for the payment year.

To improve and expand the ways we identify the TIN(s) to which we would make the APM Incentive Payment for a QP in a timelier and efficient manner, we proposed to sequentially apply the hierarchy in the following paragraph and to amend § 414.1450(c) of our regulations to reflect such hierarchy. We proposed to begin at the first step in the hierarchy, and if we are unable to identify one or more TINs with which the QP has a current affiliation at this step, we move to the next and successive steps of the hierarchy until we do identify one or more TINs with which the QP is currently affiliated at the time we are distributing APM Incentive Payments. When we identify one or more TINs with which the QP is affiliated at a step, we would make the APM Incentive Payment to those TINs. We further proposed that if we identify more than one TIN at the applicable step in the hierarchy, we will divide the APM Incentive Payment proportionally between such TINs based on the relative paid amount for Part B covered professional services that are billed through each such TINs. We proposed the hierarchy to be:

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment

base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by November 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

We sought comment on the proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed our proposed hierarchy to make the APM Incentive Payment to the QP stating the process is too complex and confusing. Those commenters stated CMS should identify a more streamlined approach where the APM Incentive Payment would be paid directly to the APM Entity.

Response: Under section 1833(z)(1)(A) of the Act, the statute provides that the APM Incentive payment is to be paid to the eligible clinician who is a QP for the year. As we explained in the CY 2017 Quality Payment Program final rule (81 FR 77487), we make the APM Incentive Payment to a TIN rather than to an individual eligible clinician. We do not believe it would be consistent with statutory intent to make the APM Incentive Payment to the APM Entity or Entities in which the QP may have participated. Rather, we believe that it would be most consistent with statutory intent to locate and make the APM Incentive Payment to the solvent TIN with the closest and most current relationship to the QP. We believe that the proposed policy provides us with the opportunity to accurately identify as many appropriate payee TINs as possible prior to making the first round of payments, and that the proposed hierarchy will allow us to identify the most appropriate TIN to which to make payment. We understand that this process is complex, but we believe that application of the hierarchy will identify an appropriate payee TIN early in the process in most cases, and therefore, be better situated to disburse APM Incentive Payments earlier in the year than was possible under our current methodology.

It has also come to our attention that there may be situations where a TIN associated with a QP may be in bankruptcy status; we would not consider this an appropriate payee TIN and would move to the next step in the hierarchy to identify another TIN to which to make the APM Incentive Payment.

Comment: Another commenter opposed our proposal that, in the event we have not identified any TIN associated with a QP to which we can make the APM Incentive Payment, we would establish a 60-day public notice process to allow QPs or other eligible clinicians who believe they are entitled to an APM Incentive Payment to notify us of their claim and provide billing information or otherwise, forfeit their claim to payment. The commenter expressed concern that because there is no official date on which future APM Incentive Payments will be made, the proposed policy is not transparent.

Response: We understand commenters' concerns about the need for CMS to complete APM Incentive Payments as quickly and predictably as possible. We proposed to introduce a cutoff date of November 1 of each payment year, or 60 days from the day on which we make the initial round of APM Incentive Payments, whichever is later; and to provide a public notice to identify the deadline by which we must receive requests from QPs or their representatives who have not received their payments. We believe establishing the cutoff date as the later of November 1 or 60 days after the initial round of payments are made creates a more predictable and finite time table for when clinicians could expect to receive their APM Incentive Payments. It is our goal to accurately make payments for all QPs as soon in the payment year as feasible. To do so, it is necessary to establish a date after which we will not consider additional inquiries or additional information from QPs or their representatives for purposes of disbursing any remaining APM Incentive Payments for the payment year.

We are finalizing without modification our proposal to adopt and use the hierarchy to identify an appropriate TIN to which to make the APM Incentive Payment for a QP. We are also finalizing our proposal that, in the event we do not identify an appropriate TIN at levels one through seven of the hierarchy, we will publish a public notice requiring the remaining QPs to come forward with their claims and provide payment information by the specified date that is the later of a 60-day deadline or November 1st of the payment year, or forfeit their claim to an APM Incentive Payment for the year.

(d) Eligible Clinicians With No Covered Professional Services in the Incentive Payment Base Period

In our experience calculating the APM Incentive Payments, it has come to our attention that there is a cohort of eligible clinicians who have been determined to be QPs for a year, and for whom an APM Incentive Payment has been calculated and in some cases paid, despite the fact that these eligible clinicians did not bill for any Part B covered professional services during the incentive payment base period. This situation arises in cases where an APM Entity is paid under the terms of the APM for supplemental services on behalf of an eligible clinician who is on their Participation List. This can occur because, for purposes of calculating the APM Incentive Payment, such supplemental service payments as described in § 414.1450(b)(7) of our regulations are considered covered professional services for purposes of calculating the APM Incentive Payment.

This scenario creates difficulty when we attempt to make the APM Incentive Payment for the QP because there are no relevant claims in our database indicating a TIN to which we should make the APM Incentive Payment. We noted in the CY 2021 PFS proposed rule (85 FR 50033 that we believe this situation is largely the result of clerical errors or delays, either in updates to the APM's Participation List that is submitted to CMS by APM participants, or through more general processes used to update an eligible clinician's Medicare enrollment information. We reminded our enrolled physicians, practitioners, group practices and other suppliers that it is their responsibility, in accordance with their APM participation and their Medicare enrollment agreement, to routinely update their APM participation lists that they submit directly to their APMs, as

well as their lists of enrolled providers assigned to their organization and associated TINs, either through the internet-based PECOS or using a CMS–855F Form. We reiterate that any payments resulting from a failure to make such updates may be considered fraud, waste, or abuse.

However, in the event that a QP's APM Incentive Payment was calculated based solely on supplemental services payments and no Medicare claims for covered professional services furnished by the QP were submitted during the incentive payment base period, we proposed to categorically assign these QPs to the list of QPs that will be given public notice requesting updated payment information within 60 day deadline or November 1st of the payment year, as described in the proposed regulation at § 414.1450(c)(8). We noted that we believe that in many if not most of these cases, such individuals have retired or otherwise ceased participation in Medicare; however, we recognized that there may be scenarios under which such individuals remain active, and noted that the proposal was meant to provide an opportunity for such clinicians to identify their current billing affiliation(s) or otherwise identify a TIN to which the APM Incentive Payment should be made.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450), we finalized policies relating to QP and Partial QP determinations. In the CY 2019 PFS final rule (83 FR 59923 through 59925), we finalized additional policies relating to QP determinations and the Partial QP election to report to MIPS.

In the CY 2021 PFS proposed rule (85 FR 50333), we proposed to:

- Update the methodology for addressing prospectively aligned beneficiaries for Threshold Score calculations and QP determinations.
- Establish a Targeted Review process for QP Determinations.

Additionally, we clarified our policies on Advanced APM determinations and QP determinations in light of questions that may arise based on the effects of the PHE for COVID–19.

We solicited comment on whether to allow an APM Entity to make the Partial QP election on behalf of all of the APM Entity's participating eligible clinicians.

(2) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we finalized that QP determinations would first be made at the APM Entity level, after which we would make further QP determinations at the individual level for eligible clinicians who are either: (1) Participating in multiple Advanced APM Entities, none of which meet the QP threshold as a group; or (2) on an Affiliated Practitioner List that is the list used for the QP determination when there are no eligible clinicians on a Participation List for the APM Entity (81 FR 77439 through 77443). As such, the QP determination at the APM Entity level generally applies to all the individual eligible clinicians who are on a Participation List of the Advanced APM. The QP determination Threshold Score calculations are aggregated using data for all eligible clinicians participating in the APM Entity on each snapshot date (March 31, June 30, August 31) during the QP Performance Period. If the APM Entity's Threshold Score meets the relevant QP threshold, all individual eligible clinicians in that APM Entity would receive the same QP determination, applied at the NPI level, for the relevant performance year (PY).

(3) Attribution of Prospectively Attributed Beneficiaries in QP Threshold Score Calculations

When making QP determinations, we include information for all attribution-eligible beneficiaries in the denominator of the patient count and payment amount methods used to calculate QP Threshold Scores as set forth in § 414.1435. ''Attribution-eligible beneficiary'' is a term defined in our regulation at § 414.1305, and the definition is generally based on the attribution methodology and rules for the particular Advanced APM. We have specified at § 414.1435(b)(3) that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4) that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups.

When making QP determinations, at the APM Entity or individual eligible clinician level, we begin by calculating Threshold Scores, which are the ratio of the payment amounts or patient counts for ''attributed beneficiaries'' to the payment amounts or patient counts for ''attribution eligible beneficiaries.'' If this ratio (the Threshold Score) for the eligible clinician or APM Entity level, as applicable, meets or exceeds the relevant QP thresholds described at § 414.1430(a), the relevant eligible clinicians will have attained QP status for a year. It has come to our attention that under our current methodology for calculating Threshold Scores, we include attribution-eligible beneficiaries in the denominator of the calculation for some APM Entities for whom those same beneficiaries could never be included in the numerator. This may happen in a scenario where a beneficiary is attributed to an APM Entity and as a result is precluded by the applicable rules for one or more APMs from attribution to other APM Entities in certain other APMs.

For example, the Shared Savings Program offers the option for ACOs to select prospective beneficiary assignment, and prospective beneficiary alignment is used in the Direct Contracting Model and Next Generation ACO Model. When beneficiaries are prospectively attributed to an ACO in one of these APMs, under the rules of precedence within the APMs themselves, those beneficiaries are generally not available for attribution to participants in some other APMs, including other ACOs, regardless of attribution methodologies. However, the population of attribution-eligible beneficiaries for APM Entities in these other APMs still includes those prospectively aligned beneficiaries. This could have the effect of disadvantaging the APM Entities to which the beneficiaries may never be attributed, because their ratio of attributed beneficiaries to attribution-eligible beneficiaries will be lower, for reasons entirely outside the control of the relevant eligible clinicians and APM Entities.

Therefore, we proposed to amend § 414.1435(c)(1) of our regulations and add a new paragraph (c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list. We noted that the effect of the proposed policy would be to remove such prospectively attributed beneficiaries from the denominators when calculating Threshold Scores for APM Entities or individual eligible clinicians in Advanced APMs that align beneficiaries retrospectively, thereby preventing dilution of the Threshold Score for the APM Entity or individual eligible clinician in an Advanced APM that uses retrospective attribution.

We sought comment on the proposals.

We received public comments on the removal of prospectively aligned beneficiaries. The following is a summary of the comments we received and our responses.

Comment: We received several of comments in support of our proposal for the removal of prospectively attributed beneficiaries. Commenters requested that we clarify the impact of the policy where beneficiaries are attribution eligible for more than one APM Entity, but the rules of one or more of the APMs would make it so that the beneficiary could only be attributed to one of the APM Entities.

Response: We appreciate the commenters support for the proposed change. The policy as proposed at § 414.1435(c)(1)(i) would have the effect of removing those beneficiaries that are prospectively attributed to an APM entity from the attribution eligible population for all other APM entities where the beneficiary would be excluded from attribution.

For example, when calculating QP determinations for a Shared Savings Program ACO, any attribution eligible beneficiaries who are prospectively assigned to another ACO, and thus have been precluded from assignment to the ACO in question, would be removed from the attribution eligible population for the ACO in our calculation. This policy will apply to cases where beneficiaries could not be attributed to multiple APM entities in a single APM or across multiple APMs.

We are finalizing this policy as proposed.

(3) Targeted Review of QP Determinations

(i) Overview

We proposed at § 414.1455(b) to establish a targeted review process for limited circumstances surrounding QP determinations. As discussed in the CY 2021 PFS proposed rule (85 FR 50334), this targeted review process would provide a systematic opportunity for eligible clinicians to bring to our attention potential clerical errors we may have made, and for us to review and make corrections if warranted. We also proposed that, after the conclusion of the time period for targeted review, there would be no further review of our QP determination with respect to an eligible clinician for the QP Performance Period.

We noted that, consistent with section 1833(z)(4) of the Act and under § 414.1455(a) of our regulations, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise, of the determination that an eligible clinician is a QP or Partial QP under § 414.1425, that an APM Entity is an Advanced APM Entity under § 414.1410, or of the determination of the amount of the APM Incentive Payment under § 414.1450.

(ii) Scope of Targeted Review

We proposed at § 414.1455(b)(1) that an eligible clinician or APM Entity may request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List used for purposes of QP determinations. We noted that if we made such a clerical error, we believe that it would be appropriate, and we proposed, to assign to the erroneously omitted eligible clinician the most favorable QP status that was determined at the APM Entity level. This would be done on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity. We believe that this policy is appropriate in these circumstances because, as a result of a CMS clerical error, the eligible clinician was not provided the opportunity to become a QP based on the level of payment amounts or patient counts through an Advanced APM for an APM Entity with which they were associated.

Alternatively, if we were to recalculate an APM Entity's Threshold Scores for one or more of the snapshot dates in the relevant QP Performance Period, and the Threshold Scores no longer met the applicable QP threshold(s), that outcome could affect all of the eligible clinicians in the APM Entity group, removing their QP status. However, the affected eligible clinicians in the APM Entity group are likely to have acted in accordance with our notification of their prior QP determination, and may not have prepared for or reported to MIPS. In correcting our own clerical error with respect to some eligible clinicians, we do not believe it would be appropriate to revisit our prior QP determinations for a broader set of eligible clinicians, thereby potentially disadvantaging those eligible clinicians in MIPS scoring through no fault of their own.

We did not proposed to conduct targeted review of potential omissions from Affiliated Practitioner Lists, as QP determinations for eligible clinicians on an Affiliated Practitioner List is made at the individual eligible clinician level for each of the QP Performance Period snapshots. As such, we would not have completed a QP determination for the QP Performance Period in question for the individual eligible clinician who has been identified prior to the targeted review if that eligible clinician was indeed omitted due to CMS clerical error. We recognize that this circumstance may occur; however, we believe this to be an infrequent occurrence. Additionally, such calculations would not be operationally feasible in order to make the APM Incentive Payment in a timely manner.

We did not propose to accept targeted review requests to correct omissions from Participation Lists of Other Payer Advanced APMs, as those lists are provided to us directly by eligible clinicians and Other Payer Advanced APMs. As such, any clerical error would not be the fault of CMS.

(iii) Targeted Review Process

In general, we proposed to align this targeted review process with the MIPS targeted review process as codified at § 414.1385. We noted this alignment would reduce the likelihood of confusion and burden on eligible clinicians and APM Entities. We proposed to redesignate our regulation that reflects the statutory preclusion of administrative or judicial review under § 414.1455(a) and (b) to § 414.1455(a)(1) and (2) and to codify our targeted review policy at § 414.1455(b).

We proposed to specify at § 414.1455(b) that either an eligible clinician or APM Entity may submit a request for targeted review. We also proposed that all requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year as described at § 414.1385(a)(2) of our regulations. The targeted review request submission period may be extended as specified by CMS. We also proposed that all requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

We proposed that a request for targeted review may be denied if the request is duplicative of another request for a targeted review; the request for targeted review is not submitted during the targeted review request submission period; or the request is outside the scope of the targeted review, as specified in § 414.1455(b)(1). We noted that, if the targeted review request is denied, there would be no change to either the QP or Partial QP determination. If the targeted review request is approved, we will assign the most favorable Threshold Score and corresponding QP status determined for

the APM Entity in which such eligible clinician participates.

We proposed that we would respond to each timely submitted request for targeted review and determine whether a targeted review is warranted.

We proposed that a request for targeted review may include additional information in support of the request at the time it is submitted. We noted that in cases where CMS requests additional information from the eligible clinician or the APM Entity group that is the subject of a request for targeted review, the information must be provided and received by CMS within 30 days of our request. Non-responsiveness to a CMS request for additional information may result in a final decision based on the information available, although another non-duplicative request for a targeted review may be submitted before the end of the targeted review request submission period.

We proposed that if targeted review requests reveal a pattern of CMS error with impacts that extend beyond the eligible clinician or clinicians who submitted such targeted review requests, we would correct any additional errors that we identify regardless of whether a targeted review was submitted for the other eligible clinicians affected.

We proposed that decisions based on the targeted review are final, and there is no further administrative review or appeal or judicial review.

We sought comment on the proposals.

We received public comments on the proposed targeted review process for QP determinations. The following is a summary of the comments we received and our responses.

Comment: We received several of comments seeking an expanded scope of Targeted Review that would include the recalculation of individual eligible clinician QP determinations.

Response: Based on past experience, our proposed targeted review process would address the vast majority of cases where a review has been necessary. Additionally, as explained in our proposal at (85 FR 50336), performing additional individual-level QP determination calculations, under our current methodology, would not be operationally feasible given statutorily determined timelines for making the APM Incentive Payment. We may consider recalculation of individual eligible clinician QP determinations in future rulemaking.

Comment: We received a comment stating that our proposed targeted review request submission period of 60 days was too short.

Response: We recognize that participants in the Quality Payment Program must meet a number of deadlines. In an effort to maximize the efficiency of the program, we believe that the benefits of aligning with the MIPS targeted review process outweigh the potential benefit of a longer timeline for the targeted review process. Additionally, any further delay of the targeted review process could further delay the process of making timely APM incentive payments.

Comment: We received several comments in support of our proposed targeted review process for QP determinations.

Response: We appreciate the support for this proposal.

We are finalizing this policy as proposed.

(4) PHE for COVID–19 Advanced APM Determination and QP Determinations

(i) Advanced APM Determinations

In the CY 2021 PFS proposed rule (85 FR 50335), we noted that due to the PHE for COVID–19 and the urgent need to address changes to certain APMs during CY 2020 to respond to the extreme shifts in the healthcare delivery system, we are exercising its enforcement discretion in connection with Advanced APM determinations. Specifically, we will not reconsider the Advanced APM determinations of APMs which have already been evaluated and determined to meet the Advanced APM criteria for CY 2019 and CY 2020 even in the event that the APMs make changes to their governing documents or operations in such a way that, if there were a redetermination, they would no longer meet the criteria to be an Advanced APM. Furthermore, we will evaluate all APMs in future years with the understanding that any provisions of the Participation Agreement or governing regulation designed in response to the PHE for COVID–19 will not be considered to the extent they would prevent the APM from meeting the Advanced APM criteria for a year.

We noted that the following APMs are considered Advanced APMs for 2020:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Comprehensive Primary Care Plus Model;
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare Accountable Care Organization (ACO) Track 1+ Model;
- Next Generation ACO Model;
- Oncology Care Model (Two-Sided Risk Arrangements);
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We note that the following APMs are considered Advanced APMs for 2019:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Comprehensive Primary Care Plus Model;
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare Accountable Care Organization (ACO) Track 1+ Model;
- Next Generation ACO Model;
- Oncology Care Model (Two-Sided Risk Arrangements);
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

(ii) QP Determinations

As discussed in the CY 2021 PFS proposed rule (85 FR 50336), we also understand that the PHE for COVID–19 may lead to the adoption of an earlier end date for certain APMs based on amendments to the APM's governing documentation, such as a Participation Agreement. For example, an Advanced APM governed by a Participation Agreement was originally scheduled to end on December 31, 2020, and the amended Participation Agreement may revise the ending date to July 1, 2020. In the event that such changes are made to a Participation Agreement to modify the end date of an Advanced APM in response to the PHE for COVID–19, we would not consider this to be a termination from an Advanced APM under § 414.1425(c)(5) or (6) of our regulations. As such, we would not revoke the QP status of eligible clinician participants in the Advanced APM on that basis.

We noted that we are aware that circumstances resulting from the PHE for COVID–19 could affect the results of QP and Partial QP determinations for the 2020 QP Performance Period, as compared to what those determinations would otherwise be in absence of the PHE for COVID–19.

However, after considering whether changes in our methodology to address the PHE for COVID–19 were warranted, we determined that any change to the QP determination methodology could have unintended negative consequences for Advanced APM participants as practice patterns have shifted even in areas with a low volume of COVID–19 cases. We noted that with the duration, scope, and severity of the PHE for COVID–19 being unknown, it is impossible to predict the potential impact both in terms of scale and which providers may be most likely to be affected. As such, we noted that we are concerned that making changes to the QP determination methodology would be more likely to inadvertently pick winners (those who would benefit from the change in methodology by achieving higher scores) and losers (those who would score better under our normal methodology than under a changed one) than it would be to generate relief from the PHE for COVID–19 across the board. We also noted that we anticipate that there would be significant challenges resulting from modifying QP calculations with so many unknown variables at play, and are concerned that any changes to our methodology could result in delays in the timing of our announcing QP status.

We discussed our belief that Advanced APM participants benefit from timely and predictable QP determinations. With all of these considerations in mind, we clarified that, apart from the exercise of enforcement discretion explained above, we would continue to perform QP determinations as established in our regulations at §§ 414.1305, 414.1425, 414.1430, 414.1435, and 414.1440 for the 2020 QP Performance Period, without modifications to address the PHE for COVID–19.

V. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

A. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless the financial relationship satisfies all requirements of an applicable exception. Section 1877 of the Act also prohibits the entity from submitting claims to Medicare or billing the beneficiary or any other individual or entity for designated health services that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following items and services are designated health services:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

B. Annual Update to the Code List

1. Background

In § 411.351, we specify that the entire scope of four categories of designated health services is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibitions:

- EPO and other dialysis-related drugs (§ 411.355(g)).
- Preventive screening tests, immunizations, and vaccines (§ 411.355(h)).

The definition of ''designated health services'' at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically included in the statutory or regulatory lists of items and services that are designated health services and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not designated health services and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

ESRD-related oral-only drugs, which are drugs or biologicals with no injectable equivalents or other forms of administration other than an oral form, were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. On December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and, thus, are designated health services.

The United States is responding to an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named ''severe acute respiratory syndrome coronavirus 2'' (''SARS–CoV–2'') and the disease it causes has been named ''coronavirus disease 2019'' (''COVID–19''). In response to the COVID–19 outbreak, the American Medical Association (AMA) has established and published new CPT codes on its website to identify currently available SARS–CoV–2 tests (see *https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-coding-and-guidance*). As of the effective date of this rule, tests for COVID–19 are designated health services, as they fall within the category of ''clinical laboratory services.''

The AMA has also established and published two new CPT codes to identify each of two COVID–19 vaccines under development, both of which are included on the Code List as qualifying for the exception at § 411.355(h). There are additional COVID–19 vaccines still under development, and we anticipate that new CPT or HCPCS codes will be established to identify those vaccines as they become available. As noted above, in order to qualify for the exception at § 411.355(h), a vaccine must be included on the Code List. Therefore, in order to ensure that any COVID–19 vaccine to which a CPT or HCPCS code applies prior to the publication of the CY 2022 Code List qualifies for the exception at § 411.355(h), we are including language in the CY 2021 Code List to address such vaccines. Under

this final regulation, the physician self-referral prohibitions do not apply to CPT code 90749 (unlisted vaccine/toxoid) *when it is used to identify a COVID–19 vaccine* or to any future CPT or HCPCS code designated for a COVID–19 vaccine. This is in addition to the other codes listed on the Code List that relate to the application of § 411.355(h). The inclusion of CPT code 90749 on the Code List is not intended and should not be considered to direct or approve the use of CPT code 90749 for the identification and billing of any COVID–19 vaccine. Coding and billing guidance is expected as COVID–19 vaccines become available and coverage and billing policies are developed. We are making this revision to the Code List to ensure that the physician self-referral law does not impede the availability of COVID–19 vaccines, when they are available, for Medicare (and other) patients. CPT and HCPCS codes assigned to any COVID–19 vaccine(s) will be posted on *CMS.gov* as they become available.

The Code List was last updated in Tables 67 and 68 of the CY 2020 PFS final rule (84 FR 63100).

2. Response to Comments

We received no comments relating to the Code List that became effective January 1, 2020.

3. Revisions Effective for CY 2021

The updated, comprehensive Code List effective January 1, 2021, is available on our website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes*.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 58 and 59 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2021. Tables 58 and 59 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis–related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

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TABLE 58: Additions to the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
0016M Onc bladder mrna 209 gen alg
0153U Onc breast mrna 101 genes
0154U Onc urthl ca rna fgfr3 gene
0155U Onc brst ca dna pik3ca gene
0172U Onc sld tum alys brca1 brca2
0174U Onc solid tumor 30 prtn trgt
0177U Onc brst ca dna pik3ca 11
0179U Onc nonsm cll lng ca alys 23
0202U Nfct ds 22 trgt sars-cov-2
0204U Onc thyr mrna xprsn alys 593
0208U Onc mtc mrna xprsn alys 108
0223U Nfct ds 22 trgt sars-cov-2
0224U Antibody sars-cov-2 titer(s)
0225U Nfct ds dna&rna 21 sarscov2
0226U Svnt sarscov2 elisa plsm srm
0240U Nfct ds vir resp rna 3 trgt
0241U Nfct ds vir resp rna 4 trgt
C9803 Hopd covid-19 spec collect
G2023 Specimen collect covid-19
G2024 Spec coll snf/lab covid-19
U0001 2019-ncov diagnostic p
U0002 Covid-19 lab test non-cdc
U0003 Cov-19 amp prb hgh thruput
U0004 Cov-19 test non-cdc hgh thru
U0005 Infec agen detec ampli probe
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No additions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
0633T Ct breast w/3d uni c-
0634T Ct breast w/3d uni c+
0635T Ct breast w/3d uni c-/c+
0636T Ct breast w/3d bi c-
0637T Ct breast w/3d bi c+
0638T Ct breast w/3d bi c-/c+
71271 Ct thorax lung cancer scr c-
92229 Img rta detc/mntr ds poc aly
A9591 Fluoroestradiol f 18
C9067 Gallium ga-68 dotatoc
C9068 Copper cu-64, dotatate, dx
C9762 Cardiac mri seg dys strain
C9763 Cardiac mri seg dys stress
RADIATION THERAPY SERVICES AND SUPPLIES
{No additions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90689 Vacc iiv4 no prsrv 0.25ml im
90694 Vacc aiiv4 no prsrv 0.5ml im
90749 Unlisted vaccine/toxoid [only when used to identify a COVID-19 vaccine]
91300 Sarscov2 vac 30mcg/0.3ml im
91301 Sarscov2 vac 100mcg/0.5ml im
Any future CPT or HCPCS code designated for a COVID-19 vaccine

[1]CPT codes and descriptions only are copyright 2020 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 59: Deletions from the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
0058T Cryopreservation ovary tiss
0111T Rbc membranes fatty acids
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No deletions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
76970 Ultrasound exam follow-up
78135 Red cell survival kinetics
RADIATION THERAPY SERVICES AND SUPPLIES
{No deletions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

[1]CPT codes and descriptions only are copyright 2020 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

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VI. Waiver of Delay in Effective Date for This Final Rule

We are committed to ensuring that we fulfill our statutory obligation to update the PFS as required by law and have worked diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accordance with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, 5 U.S.C. 808(2) provides that, if an agency finds good cause that notice and public procedures are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

As discussed in the CY 2021 PFS proposed rule (85 FR 50074, 50336), the United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS CoV 2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID 19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of International Concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

The PFS payment rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the year to which they are intended to apply. Due to CMS prioritizing efforts in support of containing and combatting the PHE for COVID–19, and devoting significant resources to that end, we announced in the proposed rule that this CY 2021 PFS final rule would not be completed in accordance with our usual schedule for this rulemaking, which aims for a publication date of at least 60 days before the start of the year to which it applies. We announced that we may need up to an additional 30 days to complete the work needed on this final rule.

Therefore, in light of the PHE for COVID–19, and the resulting strain on CMS's resources to that end, it was impracticable for CMS to publish this final rule 60 days prior to the beginning of the upcoming year, and CMS has determined that, for good cause, it would be contrary to the public interest to delay the effective date of this final rule beyond January 1, 2021; and we are waiving the 60-day delay in effective date, pursuant to 5 U.S.C. 808(2), and this CY 2021 PFS final rule will be effective 30 days after publication. Accordingly, we are providing a 30-day delay in the effective date of the final rule in accordance with the Administrative Procedure Act (5 U.S.C. 553(d)), which ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**, and section 1871(e)(1)(B)(i) of the Act, which generally prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date of its public availability.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of OMB's implementing regulations.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our burden estimates.

• The quality, utility, and clarity of the information to be collected.

• Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 60 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 60: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	125.83	125.83	251.66
Billing and Posting Clerks	43-3021	19.53	19.53	39.06
Computer Systems Analyst	15-1211	46.23	46.23	92.46
Family Medicine Physicians	29-1215	102.53	102.53	205.06
General Internal Medicine Physicians	29-1216	96.85	96.85	193.70
Health Diagnosing and Treating Practitioners	29-1000	49.26	49.26	98.52
Licensed Practical Nurse (LPN)	29-2061	23.32	23.32	46.64
Medical and Health Services Managers	11-9111	55.37	55.37	110.74
Medical Secretary	43-6013	18.31	18.31	36.62
Obstetricians and Gynecologists	29-1218	112.31	112.31	224.62
Pediatricians, General	29-1221	88.66	88.66	177.32
Physicians, All Other; and Ophthalmologists, Except Pediatric	29-1228	97.81	97.81	195.62
Psychiatrists	29-1223	105.98	105.98	211.96
Surgeons, Except Ophthalmologists	29-1248	121.17	121.17	242.34

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

For the CY 2019 and CY 2020 PFS final rules, we used the BLS wage rate for ''Physicians and Surgeons'' (occupation code 29–1060) to estimate the burden for Physicians. In BLS' most recent set of occupational wage rates dated May 2019, they have discontinued this occupation in their wage data. As a result, in order to estimate the burden for Physicians, we are using a rate of $212.78/hr which is the average of the mean wage rates for Anesthesiologists; Family Medicine Physicians; General Internal Medicine Physicians; Obstetricians and Gynecologists; Pediatricians, General; Physicians, All Other; and Ophthalmologists, Except Pediatric; Psychiatrists; and Surgeons, Except Ophthalmologists [($251.66/hr + $205.06/hr + $193.70/hr + $224.62/hr + $177.32/hr + $195.62/hr + $211.96/hr + $242.34/hr) ÷ 8].

B. Information Collection Requirements (ICRs)

1. ICRs Regarding Modifications to OTP Enrollment Process (§ 424.67)

The following requirement and burden changes will be submitted to OMB for approval under control numbers 0938–0685 and 0938–1377 (respectively, CMS–855A and CMS–855B).

a. Form CMS–855B Completion—Estimates in November 15, 2019 Final Rule

In the aforementioned November 15, 2019 final rule (84 FR 62568), we prepared estimates of the hour and cost burdens to OTPs in completing the Form CMS–855B (Medicare Enrollment Application Clinics/Group Practices and Certain Other Suppliers). We are restating them in the current rule to help stakeholders better understand the burdens associated with our changes to § 424.67.

Based on SAMHSA statistics and our internal data, we estimated in the November 15, 2019 final rule that: (1) About 1,700 certified and accredited OTPs were eligible for Medicare enrollment; and (2) 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year). This brought the total number of OTPs eligible to enroll during this 3-year period to approximately 1,900.

We projected that it would take each OTP an average of 3 hours to obtain and furnish the required information on the Form CMS–855B and a new supplement thereto designed to capture data unique to OTPs. Per our experience, we believed that the OTP's medical secretary would secure and report the data on the Form CMS–855B and supplement. We estimated that this task

would take approximately 2.5 hours, of which about 30 minutes would involve completion of the supplement. In addition, a health diagnosing and treating practitioner of the OTP would review and sign the form, a process we estimated would take 30 minutes.

Using BLS' May 2018 wage estimates, we consequently projected a first-year burden of 5,301 hours (1,767 entities × 3 hr) at a cost of $244,146 [1,767 entities ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr))]; a second-year burden of 201 hours (67 entities × 3 hr) at a cost of $9,257 [67 entities × ((2.5 hr × $35.66/hr) + (0.5 hr $98.04/hr))]; and a third-year burden of 198 hours [66 entities × 3 hr) at a cost of $9,119 (66 entities × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr))]. In aggregate, we estimated a total 3-year burden of 5,700 hours (5,301 hr + 201 hr + 198 hr) at a cost of $262,522 ($244,146 + $9,257 + $9,119). When averaged over the typical 3-year OMB approval period, we estimated an annual burden of 1,900 hours (5,700 hr/3) at a cost of $87,507 ($262,522/3).

b. Revisions to § 424.67

(1) Completion of Form CMS–855A

We foresee three main implications associated with our changes to § 424.67. First, newly enrolling OTPs would be able to complete and submit a Form CMS–855A (Medicare Enrollment Application—Institutional Providers) instead of a Form CMS–855B. Second, we anticipate that numerous OTPs that are currently enrolled via the Form CMS–855B would terminate the latter enrollments and complete/submit a Form CMS–855A application in order to bill for OTP services via the 837I. (As stated in revised § 424.67(c), an OTP cannot be enrolled via both the Form CMS–855A and Form CMS–855B; it must choose one of these two enrollment mechanisms.) Third, it is possible that some OTPs that enroll using the Form CMS–855A (pursuant to revised § 424.67(b)) would later change their enrollment to a Form CMS–855B.

In preparing the following OTP enrollment estimates, we: (1) Reviewed internal PECOS and billing data concerning existing OTP Form CMS–855 enrollments and claim submissions; and (2) considered feedback recently received from the OTP community regarding potential billing and enrollment options. Based on this, we project that over the first 3 years of our changes to § 424.67:

- Roughly one-half (or 33) of the previously estimated 67 annually enrolling OTPs (that is, in Years 2 and 3 and beyond) would elect to complete a Form CMS–855A rather than a Form CMS–855B.
- Approximately 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A.
- About 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B.

(a) New OTPs Enrolling Via the Form CMS–855A

We estimate that it would take each OTP approximately 4 hours to secure and provide the relevant data on the Form CMS–855A and the new supplement thereto (which would capture OTP-specific information). Consistent with our experience, the OTP's medical secretary would obtain and report information on the Form CMS–855A and supplement, a task that would take roughly 3.5 hours (about 30 minutes of which would involve completion of the supplement). A health diagnosing and treating practitioner of the OTP would spend 30 minutes reviewing and signing the form.

Given the preceding data, we project an annual burden for new OTPs seeking to complete a Form CMS–855A of 132 hours (4 hr × 33 OTPs) at a cost of $5,855 (33 OTPs × ((3.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). Since these OTPs would not be completing the Form CMS–855B as originally anticipated in the November 15, 2019 final rule and approved by OMB in that rule's collection of information request, we must revise the Form CMS–855B estimates identified therein. Using the hour and wage burdens from that rule, we project a Form CMS–855B annual burden reduction of 99 hours (33 OTPs × 3 hr) at a cost of $4,560 (33 OTPs × (2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)).

(b) Enrolled OTPs Transitioning to Form CMS–855A or Form CMS–855B Enrollment

As already mentioned, we believe that roughly:

++ 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A.

++ 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B.

This would involve the OTP's completion of a Form CMS–855A or Form CMS–855B application as a new enrollment. We note that in our proposed estimates, we had stated that these OTPs would also need to report the voluntary termination of their existing Form CMS–855 enrollment via the latter form (that is, if the OTP is ceasing its Form CMS–855B enrollment, it would report this via a Form CMS–855B voluntary termination submission). Upon further analysis and reflection, this step will not be necessary; termination of the prior enrollment will done by the Medicare contractor systematically. Accordingly, we are not finalizing our estimates of the burden associated with completing a Form CMS–855 voluntary termination application.

(i) Transition to Form CMS–855A Enrollment

Under our previously mentioned Form CMS–855A hour and wage estimates, we project a total burden for new Form CMS–855A enrollments pursuant to revised § 424.67(b) of 1,200 hours (300 OTPs × 4 hr) at a cost of $53,229 (300 OTPs × ((3.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). We believe this burden would be incurred exclusively in the first year following our changes; it is very likely these OTPs would wish to pursue Form CMS–855A enrollment as soon as possible in order to bill via the 837I. Over the first 3 years, the average annual burden would be 400 hours (1,200 hr/3) at a cost of $17,743 ($53,229/3).

(ii) Transition to Form CMS–855B Enrollment

In line with our hour and wage estimates previously referenced in this section VII.B.1. of this final rule, we project a total burden for new Form CMS–855B enrollments under § 424.67(c)(2) of 30 hours (10 OTPs × 3 hr) at a cost of $1,480 (10 OTPs × ((2.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). We anticipate that changes to a Form CMS–855B enrollment would occur in the second and third years following the effective date of our revisions. This is because Year 1 would mostly involve these new OTPs enrolling for the first time via the Form-855A; only in the succeeding 2 years would they switch to a Form CMS–855B enrollment. We thus project that the average annual burden in the first 3 years would be 10 hours (30 hr/3) at a cost of $469 ($1,408/3).

(2) Total Annual Burden

In light of foregoing estimates, and when averaged over the typical 3-year OMB approval period, we estimate the following:

- Form CMS–855A—The total annual increased burden would be 532 hours (132 hr + 400 hr) at a cost of $23,598 ($5,855 + $17,743).
- Form CMS–855B—We project a reduction in annual burden of −89 hours (−99 hr − 10 hr) and $4,091 (−$4,560 − $469).

(3) Application Fee

Under § 424.67(b)(2), an enrolling OTP must comply with the application fee requirements in § 424.514. This means, in short, that an OTP must pay the required application fee as part of the enrollment process. The application fee does not meet the definition of a ''collection of information'' and, as such, is not subject to the requirements of the PRA. Although we did not set out such burden under this section of the preamble, the cost is included under the Regulatory Impact Analysis section.

(4) Fingerprinting

We discussed in section III.B. of this final rule that certain OTPs are subject to the high-risk level of categorical screening under § 424.518. Said screening includes the submission of a set of fingerprints (via FBI Applicant Fingerprint Card FD–258) for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. In the November 15, 2019 final rule, we calculated the hour and cost burden associated with this activity, basing our estimates on an anticipated 1,900 total OTP enrollees over the 3-year period following publication of that rule.

We do not believe our revisions to § 424.67 would involve any additional or reduced fingerprinting burden for two reasons. First, we specify in revised § 424.67(b)(3)(ii) that, in effect, Form CMS–855B-enrolled OTPs that are changing to a Form CMS–855A enrollment need only undergo the limited level of categorical screening (§ 424.518) if they have (as part of their Form CMS–855 enrollment) already successfully completed the moderate or high level of categorical screening under that same regulatory section. Since completion of moderate or high level screening (as applicable) would have been required for Form CMS–855B OTP enrollment, these OTPs (previously estimated at 300 total) would not have to again undergo fingerprinting as part of their Form CMS–855A enrollment. Second, and with the exception of the 300 new enrollments mentioned in the previous sentence, we do not foresee additional enrolling OTPs beyond: (1) The 1,900 which we estimated in the November 15, 2019 final rule; and (2) the roughly 67 newly enrolling OTPs in Year 2 and Year 3 and annually thereafter. In other words, the only change we project would be in the type of Form CMS–855 application these OTPs may complete, not the number of anticipated enrollees. As such, the total fingerprinting burden would not change.

We received no comments regarding our ICR estimates pertaining to OTP provider enrollment.

2. ICRs Regarding the Medicare Shared Savings Program (42 CFR Part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to sections VIII.H.7.a., VIII.H.7.b., VIII.H.7.c., and VIII.H.8. of this final rule for a discussion of the impacts associated with this rule's changes to the Shared Savings Program's quality reporting requirements, beneficiary assignment methodology, and repayment mechanism requirements, and section VIII.H.7.c. of this final rule for a discussion of the impacts associated with finalization of Shared Savings Program policies established in the May 8th COVID–19 IFC.

3. ICRs Regarding the Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan § 423.160(a)

When ready, the following changes will be submitted to OMB through the standard PRA process for approval under control number 0938–TBD (CMS–10755). The standard PRA process includes the publication of 60- and 30-day **Federal Register** notices, which we expect to publish shortly after the publication of this final rule. Please note that the proposed rule indicated (85 FR 50340) that the changes would be submitted under control number 0938–0763 (CMS–R–262). However, based on internal review we have since determined that the changes should be set out under a new collection of information request. Importantly, the new collection of information request (0938–TBD; CMS–10755) has no effect on our proposed and final requirements and burden estimates. Rather, we are simply changing the location of those requirements and burden estimates. Please note that OMB will issue the new control number when ready. In the meantime it is to be determined (or ''TBD''). The new collection of information request's CMS identification number (CMS–10755) is not subject to change.

We are implementing section 2003 of the SUPPORT for Patients and Communities Act, which requires that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. We are requiring prescribers to use the NCPDP SCRIPT 2017071 standard for Electronic Prescription for Controlled Substances (EPCS) prescription transmissions beginning January 1, 2021.

In the first year of implementation, we expect that prescribers would have to revise their policies and procedures and-train staff on this new requirement. Based on our conversations with providers, EHR vendors, and Part D plans, we understand that because electronic prescribing is so widespread and vendors train the staff directly and set-up their systems, we estimate that this transition could be completed with a one-time burden of 5 hours at $36.62/hr by an Administrative Assistant or Medical Secretary. We solicited comments on this assumption and, we received several public comments related to the numbers used for this burden estimate assumption for the Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan.

Comment: Several commenters expressed concerns that CMS' proposal assumes these functionalities to be successful, when in actuality they still require significant fixes and delayed implementation timelines. Perhaps the biggest challenge clinicians will face, commenters stated, is incorporating EPCS into their EHRs, and most clinician practices are not in a position to cover the costs and acquire the necessary resources for technical or system upgrades required by EHR vendors—especially rural and small practices. Commenters stated that due to the PHE for COVID–19, many practices have been forced to delay or cancel implementation altogether of EHRs that support EPCS due to the implementation cost. Commenters expressed concern that practices that do not currently even have the capability to prescribe electronically would be forced to purchase such a software. A commenter supported the intent to facilitate efficiency, convenience, and better security with the implementation of EPCS, but encourages CMS to avoid unreasonable burden imposed upon clinicians and delay compliance until at least January 1, 2023.

Response: We are aware of the difficulties that many clinicians may face when implementing EPCS. Given that the mandate is statutory with potentially broad public health

implications, we believe a January 1, 2021 effective date complies with the statutory intent and would enable the safety and other benefits previously discussed to be put in place during the current pandemic. However, to help ensure that the burden on prescribers is not unreasonable, we will be finalizing a compliance date of January 1, 2022 such that prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the requirement. We have also adjusted the estimate of the provider burden to accurately reflect fixing any issues that may arise.

Comment: One commenter expressed concern with the health care provider burden associated with reporting EPCS transactions to CMS.

Response: Based on internal CMS data, there are 425,000 Part D prescribing practices. Based on the increasing rate of doctors conducting e-prescribing thus far in light of the current social distancing guidelines, currently, 61 percent of Part D prescribers have electronic prescribing capabilities absent the requirement. Therefore, the one-time burden to implement this provision is 828,750 hours (165,750 prescribers * 5 hr) at a cost of $30,348,825 (828,750 hr * $36.62/hr). Based on the modeling that we have seen, we have found that EHR companies provide the initial set-up of e-prescribing software free of charge, provided the prescribers pay the per transaction cost of $1.88 mentioned previously. Based on the comments received, we understand that implementing EPCS can lead to technological glitches, and then fixing those issues. We understand that the EHR companies remedy the issues free of charge. However, we understand that such fixes take time away from the medical office staff. We estimate that such fixes would take the staff approximately 1 extra hour when averaged across all prescribers. As a result, we have changed our one-time burden estimate from 5 hours to 6 hours per provider, which means a total of 994,500 hours (165,750 * 6 hr) at a cost of $36,418,590 (994,500 hr * 36.62).

4. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model

In section III.P. of this final rule, we finalize policies necessary to allow certain flexibilities for Medicare enrolled MDPP suppliers and eligible beneficiaries in the MDPP Expanded Model during a PHE. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA.

5. The Quality Payment Program (42 CFR Part 414 and Section IV. of This Final Rule)

The following QPP-specific ICRs reflect this rule's finalized policy changes and policies that have been finalized in our CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and our CY 2019 and CY 2020 PFS final rules (83 FR 59452 and 84 FR 62568, respectively).

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

The Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs. The MIPS ICRs consist of: Registration for virtual groups (see section VII.B.5.b of this final rule); QCDR self-nomination applications and other requirements (see section VII.B.5.c.(2) of this final rule); qualified registry self-nomination applications and other requirements (see section VII.B.5.c.(3) of this final rule); CAHPS survey vendor applications (see section VII.B.5.c.(4) of this final rule); Open Authorization credentialing and token request process (see section VII.B.5.d of this final rule); Quality Payment Program Identity Management Application Process (see section VII.B.5.e.(3) of this final rule); quality performance category data submission by Medicare Part B claims collection type (see section VII.B.5.e.(4) of this final rule), QCDR and MIPS CQM collection type (see section VII.B.5.e.(5) of this final rule), eCQM collection type (see section VII.B.5.e.(6) of this final rule), and CMS Web Interface collection type (see section VII.B.5.e.(7) of this final rule); CAHPS for MIPS survey beneficiary participation (see section VII.B.5.e.(8) of this final rule); group registration for CMS Web Interface (see section VII.B.5.e.(9) of this final rule); group registration for CAHPS for MIPS survey (see section VII.B.5.e.(10) of this final rule); call for quality measures (see section VII.B.5.f of this final rule); reweighting applications for Promoting Interoperability and other performance categories (see section VII.B.5.g.(2) of this final rule); Promoting Interoperability performance category data submission (see section VII.B.5.g.(3) of this final rule); call for Promoting Interoperability measures (see section VII.B.5.h of this final rule); improvement activities performance category data submission (see section VII.B.5.i of this final rule); nomination of improvement activities (see section VII.B.5.j of this final rule); nomination of MVPs (see section VII.B.5.k of this final rule); and opt-out of Physician Compare for voluntary participants (see section VII.B.5.o of this final rule).

The ICRs for Advanced APMs consist of: Partial Qualifying APM Participant (QP) election (section VII.B.5.m of this final rule); Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes (sections VII.B.5.n.(1) and (2) of this final rule); and submission of data for QP determinations under the All-Payer Combination Option (section VII.B.5.n.(3) of this final rule).

(2) Summary of Quality Payment Program Changes: MIPS

Nine MIPS ICRs [(1) QCDR self-nomination applications, (2) Qualified Registry self-nomination applications, (3) quality performance category data submission by QCDR and MIPS CQM collection type, (4) quality performance category data submission by eCQM collection type, (5) quality performance category data submission by CMS Web Interface collection type, (6) group registration for the CMS Web Interface, (7) CAHPS for MIPS survey beneficiary participation, (8) nomination of improvement activities, and (9) reweighting applications for Promoting Interoperability and other performance categories] show changes in burden due to finalized policies. In aggregate, we estimate the policies will result in a net increase in burden of +1,163 hours and +$120,391 for the 2021 MIPS performance period and −4,763 hours and −$421,117 for the 2022 MIPS performance period. The provisions discussed in section VII.A.3.g. to require QCDRs and qualified registries to conduct targeted audits if one or more deficiencies or data errors are identified in an annual data validation audit will increase the annual burden hours for both QCDRs and qualified registries by a range of 5 to 10 hours per audit. The provision discussed in section IV.A.3.c.(1)(c) of this final rule to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period will result in removal of the quality performance category data submission by CMS Web Interface collection type and group registration for the CMS Web Interface ICRs beginning with the 2022 MIPS performance period. The same provision will increase the number of respondents for both the MIPS CQM and QCDR and eCQM collection types for

the quality performance category beginning with the 2022 MIPS performance period as we assume respondents who previously submitted via the CMS Web Interface collection type will alternatively utilize one of these collection types to submit quality data in the 2022 MIPS performance period. The provision discussed in section IV.A.3.c.(1)(f)(i) of this final rule to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the CAHPS for MIPS Survey will increase the time required for beneficiaries to respond to the survey by 0.2 minutes (0.0033 hours) per beneficiary. The provision discussed in section IV.A.3.c.(3)(b)(i)(B)(bb) of this final rule to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible will increase the time by 1 hour per improvement activity nominated. Finally, the provision discussed in section IV.A.3.c.(5)(e) of this final rule to allow APM Entities the ability to submit an extreme and uncontrollable circumstances exception application will increase our estimated number of respondents by 7 APM Entities. The remaining changes to our currently approved burden estimates are adjustments due to the use of updated data sources available at the time of publication of this final rule.

We have also added two new ICRs (Open Authorization (OAuth) Credentialing and Token Request Process (see section VII.B.5.d of this final rule) and the Nomination of MVPs (see section VII.B.5.k of this final rule). The Open Authorization (OAuth) Credentialing and Token Request Process ICR reflects the burden associated with the availability of a new process for all submitter types to request approval to submit data via direct upload to CMS. The Nomination of MVPs reflects the burden associated with a new process available for all stakeholders to nominate MVPs for inclusion in the Quality Payment Program.

We are not making any changes or adjustments to the following ICRs: Registration for virtual groups, CAHPS survey vendor applications, Quality Payment Program Identity Management Application Process, group registration for CAHPS for MIPS survey; call for MIPS quality measures; and call for Promoting Interoperability measures. See section VII.B.5. of this final rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted due to two primary reasons. First, we are unable to predict with 100 percent certainty who will be a QP. New eligible clinician participants in Advanced APMs who become QPs would be excluded from MIPS reporting requirements and payment adjustments, and as such, unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians would not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict what Partial QPs, who can elect whether to report to MIPS, will do in the 2021 MIPS performance period compared to the 2019 MIPS performance period, and therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), the changes to currently approved burden estimates are adjustments based on updated projections for the 2021 MIPS performance period. We are not making any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process and submission of Data for QP determinations under the All-Payer Combination Option ICRs.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 61 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 61, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 61.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. As discussed in section IV.A.3.b. of this final rule, for clinicians in APM Entities, the APM Performance Pathway is available for both ACO and non ACOs to submit quality data. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844).

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TABLE 61: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures	As virtual group, group, individual clinicians, or APM Entity.[a]	As virtual group, group, individual clinicians, or APM Entity. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting].[b]	As virtual group, group, or individual clinicians. MIPS APMs do not submit information. CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. MIPS APMs electing the APM Performance Pathway. APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email.[d]

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Submissions by the ACO are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

[b] Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[c] The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

[d] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019 and CY 2020 PFS final rules, and continued in this

final rule create some additional data collection requirements not listed in Table 61. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs Related to MIPS Third-Party Intermediaries (See Section VII.B.5.c)

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (New) (OMB 0938–1314) (see section VII.B.5.d).

Additional ICRs Related to the Data Submission and the Quality Performance Category (See Section VII.B.5.e)

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs Related to the Promoting Interoperability Performance Category (See Section VII.B.5.g)

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs Related To Call for New MIPS Measures and Activities (See Sections VII.B.5.f, VII.B.5.h, VII.B.5.j. and VII.B.5.k)

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (OMB 0938–1314).

Additional ICRs Related to MIPS (See Section VII.B.5.o)

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs Related to APMs (See Sections VII.B.5.m and VII.B.5.n)

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule is not implementing any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any virtual group election changes under that control number.

c. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

In section IV.A.3.g. of this rule, we discuss multiple changes to the third party intermediary regulations at § 414.1400. Specifically, we are: (1) Amending current requirements for approval of third party intermediaries to take into account past performance and provision of inaccurate information regarding MIPS program requirements to eligible clinicians; (2) requiring attendance by all third party intermediaries for training and support sessions; (3) requiring that QCDRs and qualified registries must conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits; (4) incrementally increasing requirements for QCDR measure testing and clarify what is meant by full testing; and (5) requiring third party intermediaries to submit a CAP to address identified deficiencies and data issues, as well as actions to prevent recurrence. The collection of information burdens associated with each of these topics are discussed separately below for qualified registries, QCDRs, and survey vendors.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nominate process annually.[147] The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

The requirements and burden associated with this rule's data submission changes related to QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). For simplicity and due to limitations in data available, the changes in burden for QCDRs and qualified registries associated with the finalized policies regarding CAPs have been incorporated into the discussion of burden for qualified registries.

(a) Self-Nomination Process and Other Requirements

We refer readers to § 414.1400(a)(4) which states that QCDRs interested in submitting MIPS data to us on behalf of a MIPS eligible clinician, group, or virtual group will need to complete a self-nomination process to be considered for approval to do so. We also refer readers to § 414.1400(b) and the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59998 through 60000), and the CY 2020 PFS final rule (84 FR 63116 through 63121) for our previously finalized requirements and burden for self-

[147] As stated in the CY 2019 PFS final rule (83 FR 53998), health IT vendors are not included in the burden estimates for MIPS.

nomination of QCDRs and nomination of QCDR measures.

In section VII.A.3.g.(2)(a) of this rule, we are codifying that beginning with the 2023 payment year as a condition of approval each QCDR must conduct annual data validation audits that conform to the requirements in § 414.1400(b)(2)(iv), including specific obligations discussed in detail in those sections, and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits that conform to the § 414.1400(b)(2)(v) including specific obligations discussed in detail in those sections. In particular, we are codifying at § 414.1400(b)(2)(iv)(G), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. In addition, we are codifying at § 414.1400(b)(2)(v)(D), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected. We are not revising our burden estimates as a result of the provision to codify that QCDRs must conduct particular data validation audits and report data validation results because we believe the burdens of the data validation requirements are not greater than existing expectations for which we have already accounted the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938–1314 (CMS–10621).

With regard to the provision to require QCDRs to conduct targeted audits if one or more data errors are identified during data validation audits, we solicited comment on the burdens associated with the requirements for data validation audits and targeted audits, including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this provision, but received no comments. However, we are including burden estimates associated with this finalized requirement based on our best available analysis. Due to the unknown scope of patient records that may need to be audited, we estimate a range of effort to complete a targeted data audit from a minimum of 5 hours to a maximum of 10 hours at a cost ranging from $462.30 ($92.46/hr × 5 hrs) to $924.60 ($92.46/hr × 10 hrs) per targeted audit. In the 2019 MIPS performance period, 23 of the 77 QCDRs (30%) that submitted 2019 MIPS quality data were required to complete a targeted audit. Based on the results of the 2020 self-nomination period, 58 QCDRs have been approved for the 2021 MIPS performance period; assuming the same percentage, we estimate 17 QCDRs (58 × 30%) will be required to complete targeted audits. Therefore we estimate the total impact associated with QCDRs completing targeted audits will range from 85 hours (17 audits × 5 hrs/audit) at a cost of $7,859 (17 audits × $462.30/audit) to 170 hours (17 audits × 10 hrs/audit) at a cost of $15,718 (17 audits × $924.60/audit). We also discuss additional impacts of this provision in section VIII.H.15.e.(4)(d) of the Regulatory Impact Analysis.

In section VII.A.3.g.(1)(b)(iii) of this rule, we are codifying that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner and at the times, specified by CMS. Due to the nature of the information provided during these calls and because the training requirements as applied to qualified registries and QDCRs are similar to existing expectations for these entities, we are not revising our burden estimates as a result of the provisions. However, we refer readers to section VIII.H.15.e.(4)(d) of this final rule for discussion of our estimates of overall impact.

In section VII.A.3.g.(1)(b)(ii) of this rule, we discussed that the determination of whether to approve as entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with requirements of third party intermediaries for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician. Because this provision does not require any additional effort for affected entities but instead allows CMS to utilize already available information to make approval decisions, collection of information burden is unaffected for all entities. In addition, we do not anticipate this provision will result in any QCDRs electing not to self-nominate during the 2021 MIPS performance period, but believe it is possible this may occur. However, we have neither any data nor knowledge of intent from previously approved QCDRs with which to support making any changes to our burden estimates as a result of this policy. We solicited public feedback to help us determine if there are any burden implications. We did not receive comments related to this provision.

For this rule, we are adjusting the number of QCDRs we assume will self-nominate for the CY 2022 performance period from the currently approved estimate of 76 to 82, an increase of 6 from the currently approved estimate based on the number of self-nominations received during the CY 2020 nomination period which was ongoing at the time the CY 2021 PFS proposed rule was published. As discussed in section IV.A.3.g, some commenters expressed their opinion that specific requirements as well as the totality of requirements imposed on QCDRs may result in some QCDRs electing to no longer participate in QPP. Without specific information regarding the intent of each QCDR, we are unable to determine if a future decrease in QCDR participation will occur. We note that additional requirements for QCDRs were finalized in the CY 2020 PFS final rule and there was an increase in QCDRs self-nominating during the subsequent CY 2020 self-nomination period. We continue to update our burden estimates annually as we receive updated data; if QCDRs elect to end their participation in the future, we will adjust our burden estimates when the corresponding data is available.

(b) QCDR Measure Requirements

Previously, we finalized a requirement to require all QCDR measures to be fully developed and tested, with complete testing results at the clinician level, beginning with the CY 2021 performance period in the CY 2020 PFS final rule (84 FR 40816). In the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595), we delayed this requirement such that beginning with the CY 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. In section VII.A.3.g.(2)(b)(i)(B) of this rule, we discussed an incremental approach to require fully tested QCDR measures. Specifically, at § 414.1400(b)(3)(v)(C)(*1*)we are finalizing that QCDR measures that were previously approved for the CY 2020

performance period, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2022 performance period/CY 2024 payment year. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. In order for the QCDR measure to be considered for approval, testing must be completed at the clinician level by the time the measure is self-nominated. However, to be included in an MVP for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested. QCDR measures that were previously approved for the 2020 performance period, will be required to, at a minimum, be face valid prior to being self-nominated for the CY 2022 performance period, and would be required to be fully tested prior to being self-nominated for any subsequent performance periods in order to be considered for inclusion in the MIPS program. Because these provisions are not modifying the final testing requirements for QCDR measures but are instead are making modifications to the phasing and timeline for implementation of previously finalized requirements for QCDR measures other than those which will be included in an MVP, we are not making any changes to our currently approved burden estimates; however, we refer readers to section VIII.H.15.e.(4)(d) of this final rule for discussion of impacts associated with this provision. Such burden estimates and requirements are currently approved by OMB under control number 0938–1314 (CMS–10621). We solicited comment on our burden estimates and assumptions associated with these provisions regarding the testing of QCDR measures including those which will be included in an MVP. We did not receive comments related to our burden estimates and assumptions regarding the testing of QCDR measures.

We assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $92.46/hr. Considering that the time per QCDR associated with the self-nomination process range from a minimum of 5.5 hours to a maximum of 8 hours, we estimate that the annual burden will range from 451 hours (82 QCDRs × 5.5 hr) to 656 hours (82 QCDRs × 8 hr) at a cost ranging from $41,699 (451 hr × $92.46/hr) and $60,654 (656 hr × $92.46/hr), respectively. Combined with our estimate of annual burden for targeted audits, the total burden estimate ranging from 536 hours (451 + 85) at a cost of $49,559 ($41,699 + 7,859) to 826 hours (656 +170) at a cost of $76,372 ($60,654 + $15,718) (see Table 62).

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 62: Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	82	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	82
Total Applications	**82**	**82**
Total Annual Hours Per QCDR for Simplified Process (c)	5.5	5.5
Total Annual Hours Per QCDR for Full Process (d)	8	8
Total Annual Hours (e) = (a)*(c) + (b)*(d)	**451**	**656**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $92.46/hr) (f)	$508.53	$508.53
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $92.46/hr) (g)	$739.68	$739.68
Total Annual Cost (h) = (a)*(f)+(b)*(g)	**$41,699**	**$60,654**

As shown in Table 63, using the unchanged currently approved per respondent burden estimate, the increase in respondents from 76 to 82 results in an increase of between +33 (+6 respondents × 5.5 hr/respondent) and +48 hours (+6 respondents × 8 hr/respondent) at a cost of between +$3,051 (6 respondents × $508.53/respondent) and +$4,438 (6 respondents × $739.68/respondent). The finalized policy to require targeted audits as necessary results in an increase of between +85 (17 audits × 5hrs/audit) and +170 (17 audits × 10 hrs/audit) at a cost of between $7,859 (17 audits × $462.30/audit) and $15,718 (17 audits × $924.60/audit). In aggregate, we estimate a total increase in burden of between +118 hours (33 + 85) at a cost $10,911 ($3,051 + $7,859) and +218 hours (48 + 170) at a cost of $20,156 ($4,438 + $15,718).

TABLE 63: Change in Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum Burden Estimate	Maximum Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	418	608
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	536	826
Difference (c) = (b)-(a)	**+118**	**+218**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$38,648	$56,216
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$49,559	$76,372
Difference (f) = (e)-(d)	**+$10,911**	**+20,156**

(3) Qualified Registry Self-Nomination Process and Other Requirements

The requirements and burden associated with this rule's data submission changes related to qualified registries and QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to § 414.1400(a)(4) which states that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so. We also refer readers to § 414.1400 (c) and the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59997 through 59998), and the CY 2020 PFS final rule (84 FR 63114 through 63116) for our previously finalized requirements and burden for self-nomination of qualified registries.

In section IV.A.3.g.(3) of this rule, we are codifying that beginning with the 2023 payment year as a condition of approval each qualified registry must conduct annual data validation audits that conform to the requirements in § 414.1400(b)(2)(iv), including specific obligations discussed in detail in those sections and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits that conform to the § 414.1400(b)(2)(v) including specific obligations discussed in detail in those sections. In particular, we are codifying at § 414.1400(c)(2)(iii)(G), that in a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. In addition, we are codifying at § 414.1400(c)(2)(iv)(D), in a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each error type was corrected. We are not revising our burden estimates as a result of the provision to codify that qualified registries must conduct particular data validation audits and report data validation results because we believe the burdens of the data validation requirements are not greater than existing expectations for which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938–1314 (CMS–10621).

With regard to the provision to require qualified registries conduct targeted audits if one or more data errors are identified during data validation audits, we solicited comment on the burdens associated with the requirements for data validation audits and targeted audits, including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this provision, but did not receive any. However, we are including burden estimates associated with this finalized requirement based on our best available analysis. Due to the unknown scope of patient records that may need to be audited, we estimate a range of effort to complete a targeted data audit from a minimum of 5 hours to a maximum of 10 hours at a cost ranging from $462.30 ($92.46/hr × 5 hrs) to $924.60 ($92.46/hr × 10 hrs) per targeted audit. In the 2019 MIPS performance period, 37 of the 84 QCDRs (44%) that submitted 2019 MIPS quality data were required to complete a targeted audit. Based on the results of the 2020 self-nomination period, 127 qualified registries have been approved for the 2021 MIPS performance period; assuming the same percentage, we estimate 56 qualified registries (127 × 44%) will be required to complete targeted audits. Therefore we estimate the total impact associated with qualified registries completing targeted audits will range from 280 hours (56 audits × 5 hrs/audit) at a cost of $25,889 (56 audits × $462.30/audit) to 560 hours (56 audits × 10 hrs/audit) at a cost of $51,778 (56 audits × $924.60/audit). We also discuss additional impacts of this provision in section VIII.H.15.e.(4)(d) of the Regulatory Impact Analysis.

In sections VII.A.3.g.(1)(b)(iii) of this rule, we are codifying that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times specified, by CMS. Due to the nature of the information provided during these calls and because the training requirements as applied to qualified registries and QDCRs are similar to existing expectations for these entities, we are not revising our burden estimates as a result of these provisions. However, we do refer readers to section VIII.H.15.e.(4)(d) of this final rule for discussion of our estimates of the overall impact of this provision for all third party intermediaries.

In section VII.A.3.g.(1)(b)(ii) of this rule, we discussed that the determination of whether to approve an entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with requirements of third party intermediaries for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of the subpart to any eligible clinician. Because this provision does not require any additional effort for

affected entities but instead allows CMS to utilize already available information to make approval decisions, collection of information burden is unaffected for all entities. We also do not anticipate this provision will result in any qualified registries or other third party intermediaries electing not to self-nominate during the 2021 MIPS performance period, but believe it is possible this may occur. However, we have neither any data nor knowledge of intent from previously approved qualified registries or other third party intermediaries with which to support making any changes to our burden estimates as a result of this provision. We are solicited public feedback to help us determine if there are any burden implications. We did not receive comments related to burden implications of this provision.

In section VII.A.3.g.(4) of this final rule, we are modifying the existing requirement at § 1400(f)(1)(i) requiring third party intermediaries to submit to CMS by a date specified by the agency a Corrective Action Plan (CAP) to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. While the requirement for third party intermediaries to submit a CAP was finalized in our CY 2017 Quality Payment Program final rule (81 FR 77389), we did not specify the information that must be included to be included in the CAP and neglected to identify the burden associated with the required information. We are correcting that oversight in this final rule. In addition, to clarify expectations and create consistency in the content of the CAPs provide by third party intermediaries, we are revising and elaborating on the obligations for a CAP in this final rule. Specifically, we are modifying § 414.1400(f)(1)(i) such that, unless different or additional information is specified by CMS, the CAP submitted by the third party intermediary must address four issues: (1) The issues that contributed to the non-compliance; (2) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (3) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not recur in the future and (4) the detailed timeline for achieving compliance with the applicable requirements. We have historically received a total of 34 CAPs over the 3-year period of CY 2017–2019 (an average of 11.3 per year). As third party intermediaries become increasingly effective at identifying data issues and discrepancies prior to submitting data to CMS and accounting for the estimated decrease in number of QCDRs and qualified registries self-nominating in the 2020 MIPS performance period compared to the 2019 MIPS performance period (from 350 to 229), we anticipate the annual number of CAPs received to decrease to fewer than 10 per year (83 FR 59997 through 60000 and 84 FR 63114 through 63121). The effort involved in developing a CAP including the detail specified in this final rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $92.46/hr. In aggregate we estimate an annual burden of no more than 30 hours (3 hr × 10 CAPs) at a cost of $2,774 (30 hr × $92.46/hr) for third party intermediaries to develop and submit a CAP. Because we are unable to predict how many of the estimated 10 third party intermediaries submitting CAPs will be qualified registries, QCDRs, survey vendors, or health IT vendors; for simplicity we are adding the burden to the currently approved burden for qualified registries.

For this final rule, we are adjusting the number of qualified registries we assume will self-nominate for the CY 2022 performance period from the currently approved estimate of 153 to 183, an increase of 30 from the currently approved estimate and CY 2021 PFS proposed rule (85 FR 50347) based on the number of self-nominations received during the CY 2020 nomination period which was ongoing at the time the CY 2021 PFS proposed rule was published.

As discussed in section IV.A.3.g, some commenters expressed their opinion that specific requirements as well as the totality of requirements imposed on qualified registries may result in some qualified registries electing to no longer participate in QPP. Without specific information regarding the intent of each qualified registry, we are unable to determine if a future decrease in qualified registry participation will occur. We note that additional requirements for qualified registries were finalized in the CY 2020 PFS final rule and there was an increase in qualified registries self-nominating during the subsequent CY 2020 self-nomination period. We continue to update our burden estimates annually as we receive updated data; if qualified registries elect to end their participation in the future, we will adjust our burden estimates when the corresponding data is available.

We assume that the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $92.46/hr. Considering that the time per qualified registry associated with the self-nomination process range from a minimum of 0.5 hours to a maximum of 3 hours, we estimate that the annual burden will range from 91.5 hours (183 qualified registries × 0.5 hr) to 549 hours (183 qualified registries × 3 hr) at a cost ranging from $8,460 (91.5 hr × $92.46/hr) and $50,760 (549 hr × $92.46/hr), respectively (see Table 64). Combined with our estimates of burden associated with completing targeted audits and developing and submitting a CAP, our total burden estimate ranges from 401.5 hours (91.5 + 30 + 280) to 1,139 (549 + 30 + 560) at a cost between $37,123 ($8,460 + $2,774 + $25,889) and $105,312 ($50,760 + $2,774 + $51,778).

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 64: Estimated Burden for Qualified Registry Self-Nomination

	Minimum	Maximum
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	183	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	0	183
Total Applications	**183**	**183**
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Self-Nomination (e) = (a)*(c) + (b)*(d)	**91.5**	**549**
Total Annual Hours for Completion of 56 Targeted Audits (f)	**280**	**560**
Total Annual Hours for development and submittal of 30 CAPs (g)	**30**	**30**
Cost Per Simplified Process Per Qualified Registry (@ computer systems analyst's labor rate of $92.46/hr) (h)	$46.23	$46.23
Cost Per Full Process Per Qualified Registry (@ computer systems analyst's labor rate of $92.46/hr) (i)	$277.38	$277.38
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $92.46/hr) (j)	$462.30	$924.60
Cost Per CAP (@ computer systems analyst's labor rate of $92.46/hr) (k)	$277.38	$277.38
Total Annual Cost (j) = (a)*(f)+(b)*(g)+(j)*56+(k)*10	**$37,123**	**$105,312**

As shown in Table 65, using the unchanged currently approved per respondent burden estimate, the increase in respondents from 153 to 183 results in an increase of between +15 hours (+30 respondents × 0.5 hr/respondent) and +90 hours (+30 respondents × 3 hr/respondent) at a cost of between +$1,387 (+30 respondents × $46.23/respondent) and +$8,321 (+30 respondents × $277.38/respondent). The finalized policy to require targeted audits as necessary results in an increase of between +280 (56 audits × 5 hrs/audit) and +560 (56 audits × 10 hrs/audit) at a cost of between $25,889 (56 audits × $462.30/audit) and $51,778 (56 audits × $924.60/audit). When combined with our estimate of +30 hours at a cost of +$2,774 for developing and submitting CAPs, the total aggregate change ranges from +325 hours (15 + 30 + 280) to +680 hours (90 + 30 + 560) at a cost ranging from +$30,050 ($1,387 + $2,774 + $25,889) to +$62,873 ($8,321 + $2,774 + $51,778).

TABLE 65: Change in Estimated Burden for Qualified Registry Self-Nomination

	Minimum Burden Estimate	Maximum Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	76.5	459
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	401.5	1,139
Difference (c) = (b)-(a)	**+325**	**+680**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$7,073	$42,439
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$37,123	$105,312
Difference (f) = (e)-(d)	**+$30,050**	**+$62,873**

(4) Survey Vendor Requirements

This rule is not implementing any new or revised collection of information requirements or burden related to CMS-approved CAHPS for MIPS survey vendors. The requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

(5) Health IT Vendors

This rule is not implementing any new or revised collection of information requirements or burden related to health IT vendors and we do not anticipate any changes to the CEHRT process as a result of provisions promulgated in this final rule. Consequently, we are not setting out burden or making any changes under the 0938–1314 (CMS–10621) control number.

d. Open Authorization (OAuth) Credentialing and Token Request Process

In the CY 2017 Quality Payment Program final rule (81 FR 77035), we finalized the initial MIPS data submission terminology at § 414.1305 and requirements at § 414.1325, as well as the associated burden estimates. As discussed in the CY 2019 PFS final rule (83 FR 59747 through 59748), it subsequently came to our attention that the way we had previously described data submission did not precisely reflect the experience users have when submitting data to us. To ensure clarity and precision for all users, we amended the terminology at § 414.1305 to more precisely reflect this experience and made conforming amendments to § 414.1325 and other MIPS regulations. Among the newly defined terms was ''submission type'', which we defined at § 414.1305 as the mechanism by which a submitter type submits data to CMS, including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web

Interface. We stated in the CY 2019 PFS final rule that the direct submission type allows users to transmit data through a computer-to-computer interaction, such as an Application Programming Interface (API).

Beginning in the 2021 MIPS performance period, CMS will offer the Open Authorization (OAuth) Credentialing and Token Request Process. This process utilizes an API to allow users to transmit data through a computer-to-computer interaction. As such, it is an alternate means of operationalizing the previously established direct submission type. The process first requires software developers to apply for production OAuth credentials to the submissions API by registering their application so that it can interact with the system providing OAuth capabilities. Next, the developer must request a meeting with the Quality Payment Program development team. During this meeting, the requesting organization will demonstrate their application's use of OAuth to successfully submit data in the Submissions API test environment. The requesting organization will also provide documentation about their terms of service, privacy policy, and related information for review by the Quality Payment Program team. If further clarification is required about any of the documentation or application, the Quality Payment Program team will follow up with the requesting organization. Once approved, the Quality Payment Program development team will issue production OAuth credentials to the requesting organization's point of contact. Detailed instructions for the authentication process and application for organizations to request OAuth credentials are available at *https://cmsgov.github.io/qpp-submissions-docs/*.

The following burden estimates are associated with the first year of data collection for the OAuth Credentialing and Token Request Process. This process is available to all submitter types to be approved to submit data via the direct submission type. However, we assume the only parties that will elect to undergo the process will be health IT vendors or other third party intermediaries, as we believe these are the most likely parties to be developing applications. The burden associated with this ICR belongs only to the application developer; QPP participants will not be required to do anything additional to submit their data. For third party intermediaries, OAuth Credentialing will allow QPP participants to use their own QPP credentials to login through the third party intermediary's application to submit their data and view performance feedback from QPP. The burden associated with the OAuth Credentialing and Token Request Process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 and CY 2020 PFS final rules at § 414.1400(a)(2) (83 FR 60088 and 84 FR 63052) for our current policy regarding the types of MIPS data third party intermediaries may submit.

As stated in the CY 2020 PFS final rule (84 FR 63049) we are aware of stakeholders' desire to have a more cohesive participation experience across all performance categories under MIPS. We are offering this process in support of our current requirements for QCDRs and qualified registries to be able to submit data for all MIPS performance categories and health IT vendors to be able to submit data for at least one MIPS performance category (84 FR 63052 and 84 FR 63076) as well as our desire to further reduce administrative burden for clinicians to participate in MIPS. As we discuss in sections VII.B.5.e.(5), VII.B.5.e.(6), VII.B.5.(e).7, VII.B.5.g, and VII.B.5.i of this final rule individual clinicians or groups may submit their quality measures using the direct submission type via the MIPS CQM and QCDR, eCQM, or CMS Web Interface (only for the 2021 MIPS performance period) collection types as well as their Promoting Interoperability measures and improvement activities through the same direct submission type. Entities that receive approval for their applications through this process will be able to provide QPP participants a more comprehensive and less administratively burdensome experience using the direct submission type.

We estimate it would take approximately 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to provide documentation and any follow-up communication via email. We estimate that for during the 2021 MIPS performance period, 15 submitter types, consisting of third party intermediaries will complete this process to be approved for the CY 2022 submission period. We expect health IT vendors to adopt this method initially, with limited further adoption by QCDRs and Qualified Registries in future years. As shown in Table 66, we estimate it would take 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to complete the process. We estimate an annual burden of 15 hours (15 vendors × 1 hr) at a cost of $1,387 (15 hr × $92.46/hr) or $92.46 per organization ($1,387/15 vendors).

TABLE 66: Estimated Burden for the OAuth Credentialing and Token Request Process

	Burden Estimate
# of Organizations (a)	15
Total Annual Hours Per Organization to Submit (b)	1
Total Annual Hours (c) = (a)*(b)	**15**
Cost Per Organization (@ computer systems analyst's labor rate of $92.46/hr.) (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	$1,387

e. ICRs Regarding Quality Data Submission (§§ 414.1325 and 414.1335)

(1) Background

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77502 through 77503), CY 2018 Quality Payment Program final rule (82 FR 53908 through 53912), CY 2019 PFS final rule (83 FR 60000 through 60003), and the CY 2020 PFS final rule (84 FR 63121 through 63124) for our previously finalized requirements for data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: Those who submit as

MIPS eligible clinicians and those who opt to submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the first snapshot of the QP List for CY 2020 that contains participation in Advanced APMs as of March 31, 2020, that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the 2021 QP Performance Period. We assumed that all Partial QPs will participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future 2021 QP Performance Period (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). In the CY 2020 PFS final rule, we provided a set of assumptions and an approach to account for the clinicians not in small practices for whom the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data (84 FR 63121 through 63122). Because we continued to use 2018 MIPS performance period data to estimate the number of respondents in the CY 2021 PFS proposed rule, we used the same methodology. For this final rule, we are using 2019 MIPS performance period respondent data which inherently includes the impacts of the aforementioned policies finalized in the CY 2019 PFS final rule; therefore, we no longer need to make any further adjustments to account for them.

There may be an undercount in submissions because of the extreme and uncontrollable circumstances policy due to the PHE for COVID–19, that allowed clinicians to elect not to submit during the submission period for the 2019 MIPS performance period that we are using to inform our burden estimates. Despite this limitation, we believe the data from the 2019 MIPS performance period is still the best data source available as it most accurately reflects the impacts of policies finalized in previous rules and trend toward increased group reporting.

In section IV.A.3.c.(1)(c) of this rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 performance period. As a result, groups of 25 or more clinicians that previously submitted quality performance data via the CMS Web Interface will be required to use an alternate collection type beginning with the 2022 performance period, which will have to be either the MIPS CQM and QCDR or eCQM collection type. While we know that 111 groups submitted quality performance data via the CMS Web Interface in the 2019 MIPS performance period, we are not able to ascertain what alternative collection type(s) the groups would elect. In order to estimate the number of groups that will select each of these collection types, we first clustered the number of groups which submitted data via the CMS Web Interface collection type during the 2019 MIPS performance period by practice size (between 25 and 49 clinicians, between 50 and 99 clinicians, etc.). Then, for each cluster, we allocated these groups to each of the MIPS CQM and QCDR and eCQM collection types based on the percent of TINs that submitted MIPS data via these two collection types. For example, of the 1,638 TINs with a practice size of 25 to 49 clinicians which submitted data for the 2019 MIPS performance period, 1,086 (66 percent) submitted data via the MIPS CQM and QCDR collection type and 552 (34 percent) submitted data via the eCQM collection type. We applied these percentages to the 11 TINs with a practice size of 25 to 49 clinicians which submitted data via the CMS Web Interface collection type for the 2019 MIPS performance period to estimate that 7 (11 TINs × 0.73) would elect to submit data via the MIPS CQM and QCDR collection type and the remaining 4 (11 TINs × 0.27) would elect to submit data via the eCQM collection type. In total, beginning with the 2022 performance period, we estimate that 45 of the 111 groups that submitted data via the CMS Web Interface collection type for the 2019 MIPS performance period will submit quality data via the MIPS CQM and QCDR collection type and 66 groups will now submit quality data via the eCQM collection type. Note that the 111 groups is an increase of 7 from our currently approved estimate of 104 groups due to updated data (84 FR 63123) (111 groups − 104 groups). We also performed this analysis to determine the number of clinicians that would be affected and would need to submit quality data via an alternate collection type beginning with the 2022 performance period. In total, of the estimated 45,599 individual clinicians affected by this provision, we estimate that 11,432 would submit quality data as part of a group via the MIPS CQM and QCDR collection type and 34,167 would submit quality data as part of a group via the eCQM collection type. These estimates are reflected in Tables 66 and 68 and the associated changes in burden are reflected in Tables 72, 74, and 76. In aggregate, as discussed in sections VII.B.5.e.(5), (6), (7), and (9) of this final rule, we estimate the provision to sunset the CMS Web Interface measures as a collection type/submission type will result in a net decrease in quality performance data reporting burden while acknowledging the additional financial impacts on clinicians as discussed in section VIII.H.15.e.(4)(b)(i) of the Regulatory Impact Analysis.

We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2019 and CY 2020 PFS final rules (83 FR 60000 through 60001 and 84 FR 63122), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. As stated in section VII.5.a.(4) of this final rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the 2021 MIPS performance period, we used the latest QP List for the first snapshot data of the 2020 QP performance period and supplemented with clinicians who are in an APM in 2020 but not in the 2020 snapshot. This file was selected to better reflect the expected increase in the number of MIPS APMs in future years compared to previous APM eligibility files. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their

reporting as a group or individual for the CY 2019 MIPS performance period.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[148] Tables 66, 67, and 68 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 66 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2021 and 2022 MIPS performance periods based on data from the 2019 MIPS performance period.

For the 2021 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and Web Interface. For the 2022 MIPS performance period, respondents will no longer have the option to submit quality performance category data via the Web Interface. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintain consistency with previous rulemaking.

As shown in Table 66, using participation data from the 2019 MIPS performance period combined with the estimate of QPs for the 2021 performance period, we estimate a total of 651,514 clinicians will submit quality data as individuals or groups in each of the 2021 and 2022 MIPS performance periods, a decrease of 129,091 clinicians when compared to our estimate of 780,605 clinicians in the CY 2020 PFS final rule (84 FR 63122) and a decrease of 140,547 from the estimate of 792,061 in the CY 2021 PFS proposed rule due to availability of updated data from the 2019 MIPS performance period (85 FR 50350). For the 2021 performance period, we estimate 29,273 clinicians will submit data as individuals for the Medicare Part B claims collection type; 284,509 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 292,133 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 45,599 clinicians will submit as part of groups via the CMS Web Interface. Compared to the CY 2021 PFS proposed rule (85 FR 50350), these are decreases from the estimates of 94,587 and 410,518 for Medicare Part B claims and MIPS CQM and QCDR collection types, respectively; and increases from the estimates of 286,956 and 0 for the eCQM and CMS Web Interface collection types, respectively. These adjustments are due to the availability of updated data from the 2019 MIPS performance period and the delay in sunsetting the CMS Web Interface from the 2021 performance period to the 2022 performance period. For the 2022 performance period, we estimate 29,273 clinicians will submit data as individuals for the Medicare Part B claims collection type; 295,941 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 326,300 clinicians will submit data as individuals or as part of groups via the eCQM collection type.

Table 67 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

TABLE 67: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type (as Individual Clinicians or as Part of Groups)

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS performance period (excludes QPs) (a)	29,273	284,509	292,133	45,599	651,514
* 2020 MIPS performance period (excludes QPs) (b)	94,846	391,430	247,856	46,473	780,605
Difference (c)=(a)-(b)	-65,573	-106,921	+44,277	-874	-129,091
2022 MIPS performance period (excludes QPs) (d)	29,273	295,941	326,300	0	651,514
* 2020 MIPS performance period (excludes QPs) (e)	94,846	391,430	247,856	46,473	780,605
Difference (f)=(d)-(e)	-65,573	-95,489	+78,444	-46,473	-129,091

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the 2019 MIPS performance period. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 68 uses methods similar to those described to estimate the number of clinicians that will submit data as

[148] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

individual clinicians via each collection type in the 2021 and 2022 MIPS performance periods. For both the 2021 and 2022 performance periods, we estimate that approximately 29,273 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 41,340 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 42,255 clinicians will submit data as individuals using eCQMs collection type. Based on availability of updated data from the 2019 MIPS performance period, these are decreases from the currently approved estimates of 94,846 and 100,269 for the Medicare Part B claims and MIPS CQM and QCDR collection types, respectively; and an increase from the currently approved estimate of 38,935 for the eCQM collection type.

TABLE 68: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS Performance Period (excludes QPs) (a)	29,273	41,340	42,255	0	112,868
* 2020 MIPS Performance Period (excludes QPs) (b)	94,846	100,269	38,935	0	234,050
Difference (c)=(a)-(b)	-65,573	-58,929	+3,320	0	-121,182
2022 MIPS Performance Period (excludes QPs) (d)	29,273	41,340	42,255	0	112,868
* 2020 MIPS Performance Period (excludes QPs) (e)	94,846	100,269	38,935	0	234,050
Difference (f)=(d)-(e)	-65,573	-58,929	+3,320	0	-121,182

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 68 are not mutually exclusive.

Table 69 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2021 and 2022 MIPS performance periods. We assume that groups that submitted quality data as groups in the 2019 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2021 and 2022 MIPS performance periods. Specifically, for the 2021 performance period we estimate that 11,559 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 243,169 clinicians; 8,154 groups and virtual groups will submit for eCQM collection types on behalf of 249,878 eligible clinicians; and 111 groups will submit data via the CMS Web Interface on behalf of 45,599 clinicians. These are increases from the currently approved estimates of 10,949, 4,398, and 104 groups and virtual groups for the MIPS CQM and QCDR, eCQM, and CMS Web Interface collection types, respectively; due to the availability of updated data from the 2019 MIPS performance period. For the 2022 performance period we estimate that 11,604 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 254,601 clinicians and 8,220 groups and virtual groups will submit for eCQM collection types on behalf of 284,045 eligible clinicians. In section IV.A.3.(b) of this rule, we discuss the APM Performance Pathway for clinicians in APM Entities. The APM Performance Pathway is available for APM entities and as discussed in section IV.A.3.(b).(3)(a) we are finalizing an alternate measure set consisting of the CMS Web Interface measures for the 2021 MIPS performance period. However, as the data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM entities, we assume non-ACO APM Entities would participate through traditional MIPS and base our estimates on submissions received in the 2019 MIPS performance period.

TABLE 69: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type on Behalf of Clinicians

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS performance period (excludes QPs) (a)	0	11,559	8,154	111	19,824
*2020 MIPS performance period (b)	0	10,949	4,398	104	15,451
Difference (c)=(a)-(b)	0	+610	+3,756	+7	+4,373
2022 MIPS performance period (excludes QPs) (d)	0	11,604	8,220	0	19,824
*2020 MIPS performance period (e)	0	10,949	4,398	104	15,451
Difference (f)=(d)-(e)	0	+655	+3,822	-104	+4,373

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

The burden associated with the submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2021 MIPS performance period, the total number of quality measures will be 209. The new MIPS quality measures finalized for inclusion in MIPS for the 2021 MIPS performance period and future years are found in Table Group A of Appendix 1; MIPS quality measures with finalized substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures finalized for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 70, as well as counts of new, removed, and substantively changed measures.

TABLE 70: Summary of Quality Measures for the 2021 MIPS Performance Period

Collection Type	# Measures Finalized as New	# Measures Finalized for Removal	# Measures Finalized with a Substantive Change	# Measures Remaining for CY 2021*
Medicare Part B Claims Specifications	0	-9	+24	+46
MIPS CQMs Specifications	0	-11	+101	+185
eCQM Specifications	0	0	+36	+47
Survey – CSV	0	0	0	+1
CMS Web Interface Measure Specifications	0	0	+10	+10
Administrative Claims	+2	-1	0	+2
Total	+2	-14	+113	209

*A measure may be specified under multiple collection types but will only be counted once in the total.

For the 2021 MIPS performance period, there is a net reduction of 9 quality measures across all collection types compared to the 218 measures finalized for the 2020 MIPS performance period (84 FR 63124). Specifically, as discussed in section IV.A.3.c.(1)(d), we are adding 2 new administrative claims outcome measures, removing 14 quality measures, and make substantive updates to 113 quality measures. We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures.

(3) Quality Payment Program Identity Management Application Process

This rule is not implementing any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not

making any identity management application process changes under that control number.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule is not implementing any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are adjusting our currently approved burden estimates based on more recent data. The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77501 through 77504), CY 2018 Quality Payment Program final rule (82 FR 53912), CY 2019 PFS final rule (83 FR 60004 through 60005), and the CY 2020 PFS final rule (84 FR 63124 through 63126) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 67, based on 2019 MIPS performance period data, we assume that 29,273 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule is adjusting the number of Medicare Part B claims respondents from the currently approved estimate of 94,846 to 29,273 (a decrease of 65,573) based on more recent data. This is an increase/decrease of 65,314 from the estimate of 94,587 provided in the CY 2021 PFS proposed rule (85 FR 50352).

As shown in Table 71, consistent with our currently approved per response time figures, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $13.87 (0.15 hr × $92.46/hr) to 7.2 hours at a cost of $665.71 (7.2 hr × $92.46/hr). The burden will involve becoming familiar with MIPS quality measure specifications. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $46.64/hr for an LPN, 1 hour at $92.46/hr for a computer systems analyst, and 1 hour at $39.06/hr for a billing and posting clerk. We are not revising our currently approved per response time estimates.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual time ranges from 209,302 hours (7.15 hr × 29,273 clinicians) to 415,677 hours (14.2 hr × 29,273 clinicians). The estimated annual cost (per clinician) ranges from $737.03 [(0.15 hr × $92.46/hr) + (3 hr × $110.74/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (1 hr × $212.78/hr)] to a maximum of $1,388.87 [(7.2 hr × $92.46/hr) + (3 hr × $110.74/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (1 hr × $212.78/hr)]. The total annual cost ranges from a minimum of $21,575,050 (29,273 clinicians × $737.03) to a maximum of $40,656,450 (29,273 clinicians × $1,388.87).

Table 71 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

TABLE 71: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	29,273	29,273	29,273
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b)+(c)+(d)+(e)+(f)+(g)	7.15	8.05	14.2
Total Annual Hours (i) = (a)*(h)	**209,302**	**235,648**	**415,677**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr @ varying times) (j)	$13.87	$97.08	$665.71
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr @ 3 hr) (k)	$332.22	$332.22	$332.22
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr @ 1 hr) (l)	$92.46	$92.46	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr @1 hr) (m)	$46.64	$46.64	$46.64
Cost to Review Measure Specifications (@ billing clerk's labor rate of $39.06/hr @ 1 hr) (n)	$39.06	$39.06	$39.06
Cost to Review Measure Specifications (@ physician's labor rate of $212.78/hr @ 1 hr) (o)	$212.78	$212.78	$212.78
Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$737.03	$820.24	$1,388.87
Total Annual Cost (q) = (a)*(p)	**$21,575,050**	**$24,010,973**	**$40,656,450**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 72, using the unchanged currently approved per respondent burden estimates which range from $737.03 to $1,388.87, the decrease in number of respondents from 94,846 to 29,273 results in a total adjustment of between −468,847 hours (−65,573 respondents × 7.15 hr/respondent) at a cost of −$48,329,203 (−65,573 respondents × $737.03/respondent) and −931,136 hours (−65,573 respondents × 14.2 hr/respondent) at a cost of −$91,072,504 (−65,573 respondents × $1,388.87/respondent). For purposes of calculating total burden associated with the final rule as shown in Tables 100, 101, and 103, only the maximum burden is used.

TABLE 72: Adjusted Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	678,149	763,510	1,346,813
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	209,302	235,648	415,677
Difference (c) = (b)-(a)	**-468,847**	**-527,862**	**-931,136**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$69,904,253	$77,796,768	$131,728,954
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$21,575,050	$24,010,973	$40,656,450
Difference (f) = (e)-(d)	**-$48,329,203**	**-$53,785,795**	**-$91,072,504**

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77504 through 77505), CY 2018 Quality Payment Program final rule (82 FR 53912 through 53914), CY 2019 PFS final rule (83 FR 60005 through 60006), and the CY 2020 PFS final rule (84 FR 63127 through 63128) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types.

In the CY 2021 PFS proposed rule (85 FR 50290), we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period. Using the methodology discussed in section VII.B.5.e.(1) of this final rule, for the 2022 MIPS performance period, we estimate 45 additional groups will submit quality data via the MIPS CQM and QCDR collection type due to the sunsetting of the CMS Web Interface measures as a collection type/submission type after the 2021 MIPS performance period.

As noted in Tables 67, 68, and 69, and based on 2019 MIPS performance period data, for the 2021 performance period, we assume that 284,509 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 41,340 clinicians will submit as individuals and the remaining 243,169 clinicians will submit as members of 11,559 groups and virtual groups. This is a decrease of 63,496 individuals and increase of 488 groups from the estimates of 104,836 individuals and 11,071 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50353). For the 2022 performance period, we assume that 295,957 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 41,340 clinicians will submit as individuals and the remaining 254,601 clinicians will submit as members of 11,604 groups and virtual groups. Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $891.13. This consists of 3 hours at $92.46/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $110.74/hr for a medical and health services manager, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for a LPN, 1 hour at $39.06/hr for a billing clerk, and 1 hour at $212.78/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) at $92.46/hr for a computer systems analyst at a cost of $7.70 (0.083 hr × $92.46/hr). Overall we estimate a cost of $897.47/response [(3 hr × $92.46/hr) + (2 hr × $110.74/hr) + (1 hr × $212.78/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (0.083 hr × $92.46/hr)].

In aggregate, we estimate a burden of 480,482 hours [9.083 hr/response × (41,340 clinicians submitting as individuals + 11,559 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 52,899 responses)] at a cost of $47,475,487 (52,899 responses × $897.47/response) for the 2021 performance period. For the 2022 performance period, we estimate a burden of 480,890 hours [9.083 hr/response × (41,340 clinicians submitting as individuals + 11,604 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 52,944 responses)] at a cost of $47,515,873 (52,944 responses × $897.47/response). Based on these assumptions, we have estimated in Table 73 the burden for these submissions.

TABLE 73: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
# of clinicians submitting as individuals (a)	41,340	41,340
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	11,559	11,604
# of Respondents (groups plus clinicians submitting as individuals) (c)=(a)+(b)	52,899	52,944
Hours Per Respondent to Report Quality Data (d)	3	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physician Review Measure Specifications (i)	1	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083	0.083
Annual Hours Per Respondent (k)= (d)+(e)+(f)+(g)+(h)+(i)+(j)	9.083	9.083
Total Annual Hours (l) = (c)*(k)	**480,482**	**480,890**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (m)	$277.38	$277.38
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (n)	$221.48	$221.48
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (o)	$92.46	$92.46
Cost LPN Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (p)	$46.64	$46.64
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (q)	$39.06	$39.06
Cost Physician Review Measure Specifications (@ physician's labor rate of $212.78/hr) (r)	$212.78	$212.78
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $92.46/hr) (s)	$7.70	$7.70
Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$897.47	$897.47
Total Annual Cost (u) = (c)*(t)	**$47,475,487**	**$47,515,873**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 74, using the unchanged currently approved per respondent burden estimate, the decrease of 58,319 respondents from 111,218 to 52,899 for the 2021 performance period results in a decrease of −529,711 hours (−58,319 respondents × 9.083 hr/respondent) and −$52,339,796 (−58,319 respondents × $897.47/respondent). For the 2022 performance period, the decrease of 58,274 respondents from 111,218 to 52,944 results in a decrease of −529,303 hours (−58,264 respondents × 9.083 hr/respondent) and −$52,299,410 (−58,274 respondents × $897.47/respondent).

TABLE 74: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	1,010,193	1,010,193
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	480,482	480,890
Difference (c) = (b)-(a)	**-529,711**	**-529,303**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$99,815,283	$99,815,283
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$47,475,487	$47,515,873
Difference (f) = (e)-(d)	**-$52,339,796**	**-$52,299,410**

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77505 through 77506), CY 2018 Quality Payment Program final rule (82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), and the CY 2020 PFS final rule (84 FR 63128 through 63130) for our previously finalized requirements and burden for quality data submission via the eCQM collection types.

In the CY 2021 PFS proposed rule (85 FR 50290), we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period. Using the methodology discussed in section VII.B.5.e.(1) of this final rule, for the 2022 MIPS performance period, we estimate 66 additional groups will submit quality data via the eCQM collection type due to the sunsetting of the CMS Web Interface measures as a collection type/submission type after the 2021 MIPS performance period.

Based on 2019 MIPS performance period data, for the 2021 performance period, we assume that 292,133 clinicians will elect to use the eCQM collection type; 42,255 clinicians are expected to submit eCQMs as individuals; and 8,154 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 249,878 clinicians. This is an increase of 778 individuals and 3,680 groups from the estimates of 41,477 individuals and 4,474 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50355). For the 2022 performance period, we assume that 320,003 clinicians will elect to use the eCQM collection type; 42,255 clinicians are expected to submit eCQMs as individuals; and 8,220 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 284,045 clinicians. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $92.46/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for an LPN, and 1 hour at $39.06/hr for a billing clerk. Overall we estimate a cost of $797.34/response [(2 hr × $92.46/hr) + (2 hr × $110.74/hr) + (1 hr × $212.78/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr)].

In aggregate, for the 2021 performance period, we estimate a burden of 403,272 hours (8 hr × 50,409 groups and clinicians submitting as individuals) at a cost of $40,193,112 (50,409 responses × $797.34/response). For the 2022 performance period, we estimate a burden of 403,800 hours (8 hr × 50,475 groups and clinicians submitting as individuals) at a cost of $40,245,737 (50,475 responses × $797.34/response). Based on these assumptions, we have estimated in Table 75 the burden for these submissions.

TABLE 75: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

	2021 Performance Period Burden estimate	2022 Performance Period Burden estimate
# of clinicians submitting as individuals (a)	42,255	42,255
# of Groups submitting via EHR on behalf of individual clinicians (b)	8,154	8,220
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	50,409	50,475
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physicians Review Measure Specifications (i)	1	1
Annual Hours Per Respondent (j)=(d)+(e)+(f)+(g)+(h)+(i)	8	8
Total Annual Hours (k)=(c)*(j)	**403,272**	**403,800**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (l)	$184.92	$184.92
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (m)	$221.48	$221.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (n)	$92.46	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (o)	$46.64	$46.64
Cost to Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (p)	$39.06	$39.06
Cost to D21Review Measure Specifications (@ physician's labor rate of $212.78/hr) (q)	$212.78	$212.78
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$797.34	$797.34
Total Annual Cost (s) = (c)*(r)	**$40,193,112**	**$40,245,737**

As shown in Table 76, using the unchanged currently approved per respondent burden estimate, the increase of 7,076 respondents from 43,333 to 50,409 for the 2021 performance period results in a total difference of +56,608 hours (+7,076 respondents × 8 hr/respondent) at a cost of +$5,641,978 (+7,076 respondents × $797.34/respondent). For the 2022 performance period, the increase of 7,142 respondents from 43,333 to 50,475 results in a total difference of +57,136 hours (+7,142 respondents × 8 hr/respondent) at a cost of +$5,694,603 (+7,142 respondents × $797.34/respondent).

TABLE 76: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	346,664	346,664
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	403,272	403,800
Difference (c) = (b)-(a)	**+56,608**	**+57,136**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$34,551,134	$34,551,134
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$40,193,112	$40,245,737
Difference (f) = (e)-(d)	**+$5,641,978**	**+$5,694,603**

(7) Quality Data Submission via CMS Web Interface

The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2021 PFS proposed rule, we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period (85 FR 50290). As a result, we did not provide a burden estimate for quality data submission via the CMS Web Interface for the 2021 performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period; therefore, we are now providing a burden estimate for the 2021 MIPS performance period.

We assume that 111 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the 2019 MIPS performance period. This is an increase of 7 groups from the currently approved number of 104 groups provided in the CY 2020 PFS final rule (84 FR 63130) due to receipt of more current data. We estimate that 45,599 clinicians will submit as part of groups via this method, a decrease of 874 from our currently approved estimate of 46,473 clinicians.

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. Our burden estimate for submission includes the time (61.67 hours) needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate a burden for the 2021 performance period of 6,845 hours (111 groups × 61.67 hr) at a cost of $632,923 (6,845 hr × $92.46/hr). For the 2022 performance period, we estimate a burden of zero due to our assumption that all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types. Based on the assumptions discussed in this section, Table 77 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 77: Estimated Burden for Quality Data Submission via the CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
# of Eligible Group Practices (a)	111	0
Total Annual Hours Per Group to Submit (b)	61.67	61.67
Total Annual Hours (c) = (a)*(b)	6,845	0
Cost Per Group to Report (@ computer systems analyst's labor rate of $90.02/hr.) (d)	$5,701.70	$5,701.70
Total Annual Cost (e) = (a)*(d)	$632,923	$0

As shown in Table 78, using our unchanged currently approved per respondent burden estimate, the increase in number of respondents results in a total adjustment of +432 hours (+7 respondents × 61.67 hr) at $39,914 (+431.7 hr × $92.46/hr) for the 2021 MIPS Performance Period. For the 2022 MIPS performance period, our burden estimate is 0 hours and $0.

TABLE 78: Change in Estimated Burden for Quality Data Submission via the CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	6,413	6,413
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	6,845	0
Difference (c) = (b)-(a)	**+432**	**-6,413**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$593,009	$592,977
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$632,923	$0
Difference (f) = (e)-(d)	**+$39,914**	**-$592,977**

(8) Beneficiary Responses to CAHPS for MIPS Survey

In this final rule, we are revising the requirements for the CAHPS for MIPS survey which will result in updates to the CAHPS for MIPS survey instrument which is currently approved by OMB under control number 0938–1222 (CMS–10450). The survey instrument is not ready at this time, therefore we will make the updated survey instrument and burden available for public review through a stand-alone non-rule **Federal Register** notice that is expected to publish in early CY 2021.

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509), CY 2018 Quality Payment Program final rule (82 FR 53916 through 53917), and CY 2019 PFS final rule (83 FR 60009 through 60010 for our previously finalized requirements and burden for beneficiary responses to the CAHPS for MIPS survey.

In section IV.A.3.c.(1)(f)(ii), we are: (1) Revising and codifying at § 414.1305 the definition of primary care services used in the MIPS assignment methodology to include virtual primary care visits and telehealth visits to determine patient assignment to groups starting in the 2021 CAHPS for MIPS survey; and (2) revising the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings. We do not believe any of these provisions will impact the number of groups electing to have the CAHPS for MIPS survey administered on their behalf, the number of beneficiaries who complete the survey, or the time required for a beneficiary to complete the survey. In the future, if additional data becomes available, we may revise our assumptions at that time.

Additionally, in IV.A.2.c.(1)(e)(i), we are adding a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the performance year 2021 CAHPS for MIPS Survey. Currently, the CAHPS for MIPS survey instrument contains 58 questions and we estimate it requires a beneficiary 12.9 minutes on average to complete it, or approximately 0.2 minutes per question. We assume this provision will result in 1 additional question being added to the survey which would result in the total time to complete the survey increasing from 12.9 minutes (0.215 hr) to 13.1 minutes (0.2183 hr) per beneficiary, or an increase of 0.2 minutes (0.0033 hr).

Based on the number of beneficiaries who completely or partially responded to the survey in the 2019 MIPS performance period, we assume that 29,952 beneficiaries will respond to the survey during the 2021 MIPS performance period. This is a decrease of 9,087 from our currently approved estimate of 39,039 beneficiaries and a decrease of 37 beneficiaries from the CY 2020 PFS proposed rule due to updated data. Using this updated number of respondents and our revised estimate of burden per respondent, we estimate an annual burden of 6,540 hours (29,952 respondents × 0.2183 hr/respondent) at a cost of $168,196 (6,540 hr × $25.72/hr). Table 79 shows the estimated annual burden for beneficiaries to participate in the CAHPS for MIPS Survey.

TABLE 79: Estimated Burden for Beneficiary Responses to CAHPS for MIPS Survey

	Burden Estimate
Number of beneficiaries who will respond to the survey (a)	29,952
Number of hours per beneficiary respondent (b)	0.2183
Total Annual Hours (c) = (a)*(b)	**6,540**
Labor rate for a beneficiary (d)	$25.72/hr
Total Annual Cost (e) = (a)*(d)	**$168,196**

*Due to burden being estimated in fractions of minutes and hours, totals may reflect impact of rounding.

Independent of the change in burden per respondent, the decrease of −9,087 respondents from 39,039 to 29,952 results in a difference of −1,954 hours (−9,087 respondents × 0.215 hr/respondent) at a cost of −$50,250 (−9,087 hrs × $25.72/hr). Accounting for the change in number of respondents, the increase in burden per respondent from 0.215 hours to 0.2183 hours results in a difference of +100 hours (29,952 respondents × 0.0033 hr/respondent) at a cost of $2,568 (100 hrs × $25.72/hr). As shown in Table 80, the aggregate change in burden is −1,854 hours (100 hours–1,954 hours) at a cost of −$47,682 ($2,568 − $50,250).

TABLE 80: Change in Estimated Burden for Beneficiary Responses to CAHPS for MIPS Survey

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	8,393
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	6,540
Difference (c) = (b)-(a)	**-1,854**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$215,878
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$168,196
Difference (f) = (e)-(d)	**-$47,682**

The revised survey and burden will be released to the public via the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

(9) Group Registration for CMS Web Interface

The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2021 PFS proposed rule, we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period (85 FR 50290). As a result, we did not provide a burden estimate for group registration for the CMS Web Interface for the 2021 performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period; therefore, are now providing a burden estimate for both the 2021 and 2022 MIPS performance period.

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an online registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 81, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $92.46/hr for a computer systems analyst (or their equivalent) to register the group.

In this rule, we are adjusting the number of respondents from 69 to 90 based on more recent data; an increase of 21 from the 69 groups currently approved by OMB and our estimate in the CY 2021 PFS proposed rule (85 FR 50358). Because we are finalizing to sunset the CMS Web Interface beginning with the 2022 MIPS performance period, it is possible that fewer groups will elect to register to submit quality data for the first time in the performance year prior to the collection type/submission type no longer being available; however, we currently have no data with which to estimate what the associated reduction may be. Therefore, we continue to assume that approximately 90 groups will elect to use the CMS Web Interface for the first time during the 2020 MIPS performance period based on the number of new registrations received during the CY 2020 registration period. As shown in Table 81, we estimate a burden of 22.5 hours (90 new registrations × 0.25 hr/registration) at a cost of $2,080 (22.5 hr × $92.46/hr).

TABLE 81: Estimated Burden for Group Registration for CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Number of New Groups Registering for CMS Web Interface (a)	90	0
Annual Hours Per Group (b)	0.25	0.25
Total Annual Hours (c) = (a)*(b)	22.5	0
Labor rate for a computer systems analyst (d)	$92.46/hr	$92.46/hr
Total Annual Cost (e) = (a)*(d)	$2,080	$0

As shown in Table 82 using our unchanged currently approved per respondent burden estimates, the increase in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of +5.25 hours (+21 respondents × 0.25 hours/respondent) at a cost of $485 (+21 groups × 0.25 hr × $92.46/hr) for the 2021 MIPS performance period. For the 2022 MIPS performance period, our burden estimate is 0 hours and $0.

TABLE 82: Change in Estimated Burden for Group Registrations for the CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	17.25	17.25
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	22.5	0
Difference (c) = (b)-(a)	**+5.25**	**-17.25**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$1,595	$1,595
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$2,080	$0
Difference (f) = (e)-(d)	**+$485**	**-$1,595**

(10) Group Registration for CAHPS for MIPS Survey

This rule is not implementing any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any changes to burden for CAHPS for MIPS survey group registration under that control number.

f. ICRs Regarding the Call for MIPS Quality Measures

This rule is not implementing any new or revised collection of information requirements or burden related to the call for MIPS quality measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any call for MIPS quality measure changes under that control number.

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the 2021 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), CY 2019 PFS final rule (83 FR 60011 through 60012), and the CY 2020 PFS final rule (84 FR 63134 through 63135) for our previously finalized requirements and burden for reweighting applications for Promoting Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting for the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

Table 83 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received by December 31, 2019 for the 2019 MIPS performance period, we assume 51,098 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification and an additional 994 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activity performance categories due to an extreme or uncontrollable circumstance, for a total of 52,092 reweighting applications submitted. This is an increase of 21,472 respondents compared to our currently approved estimate of 30,620 respondents (84 FR 63134). Similar to the data used to estimate the number of respondents in the CY 2020 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. Our respondent estimate is also based on data that does not include applications submitted during the extended period ending April 30, 2020 due to the PHE for COVID–19, as we do not believe it would be an accurate basis for future estimates of application submissions. Of our total respondent estimate of 52,092, we estimate that 35,986 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 16,106 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

In section IV.A.3.c.(5)(e), we discussed that, beginning with the 2022 MIPS payment year (2020 performance year), APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. As previously discussed in section VII.B.5.a.(4) of this final rule, due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. Therefore, we limited our analysis to ACOs that were eligible for an exception due to extreme and uncontrollable circumstances during the 2019 MIPS performance period and elected not to report quality data. Based on this data, we estimate 7 APM Entities will submit an extreme and uncontrollable circumstances exception application for the 2021 MIPS performance period. Combined with our aforementioned estimate of 52,092 eligible clinicians and groups, the total estimated number of respondents for the 2021 MIPS performance period is 52,099.

The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances

impair the clinician or group's ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced. We continue to estimate it will take 0.25 hours at $92.46/hr for a computer system analyst to complete and submit the application. As shown in Table 83, we estimate an annual burden of 13,025 hours (52,099 applications × 0.25 hr/application) and $1,204,268 (13,025 hr × $92.46/hr).

TABLE 83: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	35,986
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	16,106
# APM Entities requesting Extreme and Uncontrollable Circumstances exception	7
Total Applications Submitted (c)	52,099
Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e)=(a)*(c)	**13,025**
Labor Rate for a computer systems analyst (f)	$92.46/hr
Total Annual Cost (g)=(a)*(f)	**$1,204,268**

As shown in Table 84, using our unchanged currently approved per respondent burden estimate, the increased number of respondents results in a total adjustment of 5,370 hours (21,479 respondents × 0.25 hr/respondent) and $496,487 (5,370 hr × $92.46/hr).

TABLE 84: Adjusted Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	7,655
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	13,025
Difference (c) = (b)-(a)	**+5,370**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$707,781
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$1,204,268
Difference (f) = (e)-(d)	**+$496,487**

(3) Submitting Promoting Interoperability Data

We did not propose any new or revised collection of information requirements related to the submission of data for the Promoting Interoperability performance category. However, we are adjusting our currently approved burden estimates based on more recent data. The burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509 through 77511), CY 2018 Quality Payment Program final rule (82 FR 53919 through 53920), CY 2019 PFS final rule (83 FR 60013 through 60014), and the CY 2020 PFS final rule (84 FR 63135 through 63137) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In this final rule, we did not propose any changes to our current criteria for automatic reweighting of the Promoting Interoperability performance category for certain MIPS eligible clinicians or MIPS eligible clinicians who have experienced a significant hardship or decertification of an EHR.

In section IV.A.3.c.(4)(b) of this rule, we are adding § 414.1320(g)(1), which would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Because this does not change the number of required Promoting Interoperability measures that must be reported, we are not making any changes to our burden assumptions.

In section IV.3.c.(4)(c)(ii)(b) we are adding the HIE bi-directional exchange measure for the 2021 performance period and subsequent years as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information

measure. This provision provides clinicians the option of either reporting the new measure or the two existing measures. Because the new HIE measure is an optional alternative instead of a new requirement and the provision does not change the number of required Promoting Interoperability measures that must be reported, we are not making any changes to our burden assumptions.

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264) and CY 2019 PFS final rule (83 FR 59822–59823), we established that eligible clinicians in MIPS APMs (including the Shared Savings Program) may report for the Promoting Interoperability performance category as an APM Entity group, individuals, or a group. Because we are not making changes at § 414.1375 to the scoring for APM entities as a result of our provision in section IV.A.3.(b) of this final rule to establish an APM Performance Pathway, our reporting assumptions for clinician in MIPS APMs remains unchanged.

As shown in Table 85, based on data from the 2019 MIPS performance period, we estimate that a total of 53,636 respondents consisting of 42,110 individual MIPS eligible clinicians and 11,526 groups and virtual groups will submit Promoting Interoperability data. Since our CY 2020 PFS final rule estimated 74,281 respondents, this represents a decrease of 20,645 respondents (53,636 respondents − 74,281 active respondents). This is a decrease of 20,636 individuals and 3,227 groups from the estimates of 62,746 individuals and 14,753 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50360).

We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APM Performance Pathway. As a result, we do not anticipate any change in burden. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 through 59823). Burden estimates for this final rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants. As we receive updated information which reflects the actual number of Promoting Interoperability data submissions submitted by Shared Savings Program ACO participants, we will update our burden estimates accordingly.

TABLE 85: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians

	# of Respondents
Number of individual clinicians to submit Promoting Interoperability (a)	42,110
Number of groups to submit Promoting Interoperability (b)	11,526
Total Respondents in 2021 MIPS performance period (CY 2021 Final Rule) (c) = (a) + (b)	53,636
*Total Respondents in 2020 MIPS performance period (CY 2020 Final Rule) (d)	74,281
Difference (e) = (c) – (d)	-20,645

We continue to estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As shown in Table 86, the total burden estimate for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 143,029 hours (53,636 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $13,224,492 (143,029 hr × $92.46/hr)).

TABLE 86: Estimated Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	42,110
Number of groups to submit Promoting Interoperability (b)	11,526
Total (c) = (a) + (b)	53,636
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a)*(b)	**143,029**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	**$13,224,492**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 87, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −55,054 hours (−20,645 respondents × 2.67 hr/respondent) at a cost of −$5,090,231 (−55,054 hr × $92.46/hr).

TABLE 87: Adjusted Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	198,083
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	143,029
Difference (c) = (b)-(a)	**-55,054**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$18,314,723
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$13,224,492
Difference (f) = (e)-(d)	**-$5,090,231**

h. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule is not implementing any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

i. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

We are adjusting our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512), CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922), CY 2019 PFS final rule (83 FR 60015 through 60017), and the CY 2020 PFS final rule (84 FR 63138 through 63140) for our previously finalized requirements and burden for submission of data for the Improvement Activities performance category.

In this final rule, we did not make any changes to our requirements associated with criteria for attesting to specific improvement activities.

As discussed in section IV.A.3.c.(3)(b)(iii) of this rule, we are finalizing the removal of one obsolete improvement activity, modification of two existing improvement activities, and adoption of the COVID–19 improvement activity added via IFC. We refer readers to Appendix 2 of this final rule for further details. Because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform, we do not expect these provisions to affect our currently approved information collection burden estimates.

In section IV.A.3.b.(3)(c) of this rule, we outline how we would assign a score for the Improvement Activities performance category for MIPS APMs. We will assign Improvement Activities scores to APM participants in the APP based on the requirements of participation in APMs. To develop the Improvement Activities score for MIPS APMs, we will compare requirements of the APM with the list of Improvement Activities measures for the applicable year, and score those measures as they would otherwise be scored according to § 414.1355. In the event a MIPS APM participant does not actually perform an activity for which Improvement Activities credit would otherwise be assigned under this provision, the MIPS APM participant would not receive credit for the associated Improvement Activity. In the event that the assigned score does not represent the maximum improvement activities score, we specify that MIPS eligible clinicians reporting through the APP would have the opportunity to report additional improvement activities that then would be applied towards their scores. Our burden estimates assume there will be no improvement activities burden for MIPS APM participants electing the APP. We will assign the improvement

activities performance category score at the APM Entity level.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. In the 2020 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category through a MIPS CQM or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type, the policies requiring qualified registries and QCDRs to be able to submit data for all three of the MIPS performance categories identified in § 414.1400(a)(2) will help to alleviate this issue. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Similar to our assumption in the CY 2018 Quality Payment Program final rule, our burden estimates assume that the MIPS APM models for the 2021 MIPS performance period will qualify for the maximum improvement activities performance category score and, as such, APM Entities will not submit any additional improvement activities. (82 FR 53921 through 53922).

As represented in Table 88, based on 2019 MIPS performance period data, we estimate that a total of 79,927 respondents consisting of 62,603 individual clinicians and 17,324 groups will submit improvement activities during the 2021 MIPS performance period. Since our currently approved burden sets out 103,813 respondents, this represents a decrease of − 23,886 respondents (79,927 respondents—103,813 active respondents). This is a decrease of 23,157 individuals and an increase of 610 groups from the estimates of 85,760 individuals and 16,714 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50362).

As discussed in sections VII.B.5.e.(2) and VII.B.5.g.(3) of this final rule regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we have updated our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or members of an ACO in the 2019 MIPS performance period but will be in the 2021 MIPS performance period, and will therefore not be required to submit improvement activities data.

TABLE 88: Estimated Number of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

	Count
# of clinicians to participate in improvement activities data submission as individuals during the 2021 MIPS performance period (a)	62,603
# of Groups to submit improvement activities on behalf of clinicians during the 2021 MIPS performance period (b)	17,324
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2020 MIPS performance period (CY 2021 Final Rule) (c) = (a) + (b)	79,927
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (CY 2020 Final Rule) (d)	103,813
Difference (e)=(c)-(d)	**-23,886**

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the CY 2020 PFS final rule, we continue to estimate that the per response time required per individual or group is 5 minutes for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials (84 FR 63140).

As shown in Table 89, we estimate an annual burden of 6,661 hours (79,927 responses × 5 minutes/60) and $615,838 (6,661 hr × $92.46/hr)).

TABLE 89: Estimated Burden for Improvement Activities Submission

	Burden Estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a)	79,927
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c) = (a)*(b)	**6,661**
Labor rate for a computer systems analyst to submit improvement activities (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$615,838**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 90, using our unchanged currently approved per respondent burden estimate, the decrease of −23,886 in the number of respondents results in an adjustment of −1,990 hours (−23,886 responses × 5 minutes/60) at a cost of −$184,041 (−1,990 hr × $92.46/hr).

TABLE 90: Adjusted Burden for Improvement Activities Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	8,651
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	6,661
Difference (c) = (b)-(a)	**-1,990**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$799,879
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$615,838
Difference (f) = (e)-(d)	**-$184,041**

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53922), CY 2019 PFS final rule (83 FR 60017 through 60018), and the CY 2020 PFS final rule (84 FR 63141) for our previously finalized requirements and information collection burden for the nomination of improvement activities.

In the CY 2018 Quality Payment Program final rule, for the 2018 and future MIPS performance periods, stakeholders were provided an opportunity to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). In section IV.A.3.c.(3)(b)(i)(B)(bb) of this rule, we are requiring nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible. Similar to the burden assumptions finalized in the CY 2020 PFS final rule for the nomination of quality measures, we believe this will require approximately 0.6 hours at $110.74/hr for a medical and health services manager and 0.4 hours at $212.78/hr for a physician to research existing measures and provide a rationale for the linkage (84 FR 63132). We previously estimated it would require 1.2 hours for a medical and health services manager or equivalent and 0.8 hours for a physician to nominate an improvement activity (84 FR 63141). Combined with our currently approved burden estimate, we now estimate 1.8 hours at $110.74/hr for a medical and health services manager or equivalent and 1.2 hours at $212.78/hr for a physician to nominate an improvement activity. This represents a change of +0.6 hours (1.8 hr—1.2 hr) for a medical and health services manager or equivalent and +0.4 hours (1.2 hr—0.8 hr) for a physician and an overall increase of 1 hour.

In section IV.A.3.c.(3)(b)(i)(A)(bb), we are making an exception to the established timeframe for nomination of improvement activities, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). While we expect additional nominations may be received as a result of this change, we do not have any data with which to estimate what the additional number may be. As a result, our burden estimate remains unchanged due to this provision. Additionally, in section IV.A.3.c.(3)(b)(ii)(B), beginning with the CY 2021 performance period and future years, we will consider agency-nominated improvement activities. Because these nominations would be submitted by federal agencies, the associated time is exempt from the PRA, and therefore, not included in our estimates. We also refer readers to

section VIII.H.15.e.(4)(c) where we discuss our impact analysis.

Due to the PHE for COVID–19, we continue to use our currently approved assumption that we will receive 31 nominations of new or modified activities which will be evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2022 Improvement Activities Inventory as we believe this estimate is more realistic than basing our estimate on the number of nominations received during the 2020 Annual Call for Activities.

As shown in Table 91, we estimate an annual information collection burden of 93 hours (31 nominations × 3 hr/nomination) at a cost of $14,095 (31 × [(1.8 hr × $110.74/hr) + (1.2 hr × $212.78/hr)]).

TABLE 91: Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
# of Nominations of New Improvement Activities (a)	31
# of Hours Per Medical and Health Services Manager to Identify and Nominate Activity (b)	1.8
# of Hours Per Physician to Identify Activity (c)	1.2
Annual Hours Per Respondent (d)= (b) + (c)	3.0
Total Annual Hours (e) = (a)*(d)	**93**
Cost to Identify and Submit Activity (@ medical and health services manager's labor rate of $110.74/hr) (f)	$199.33
Cost to Identify Improvement Activity (@ physician's labor rate of $212.78/hr) (g)	$255.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$454.67
Total Annual Cost (i)=(a)*(h)	**$14,095**

As shown in Table 92, using our unchanged estimate of the number of activities nominated, the increase in the burden per nomination results in a change of 31 hours (31 nominations × 1 hr/nomination) at a cost of $4,698 (31 activities × [(0.6 hr × $110.74/hr) + (0.4 hr × $212.78/hr)]).

TABLE 92: Change in Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	62
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	93
Difference (c) = (b)-(a)	**+31**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$9,396
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$14,095
Difference (f) = (e)-(d)	**+$4,698**

k. Nomination of MVPs

The following reflects the burden associated with the first year of data collection associated with a new process available for all clinicians/third party intermediaries to nominate MVPs for inclusion in the Quality Payment Program. The requirements and burden associated with the Nomination of MVPs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning with the 2022 performance period, we are requiring stakeholders to formally submit their MVP candidates utilizing a standardized template, which will be published in the QPP resource library for future implementation. Stakeholders should submit all information including a description of how their MVP abides by the MVP development criteria as described in section IV.A.3.a.(2)(a)(i) of this final rule, and provide rationales as to why specific measures and activities were chosen to construct the MVP. As MVP candidates are received, they will be reviewed, vetted, and evaluated by CMS and our contractors to determine if the MVP is feasible and ready for inclusion in the upcoming performance period. For the 2021 MIPS performance period, we assume 25 MVP nominations will be received and the estimated time required to submit all required information is 12 hours per nomination. We solicited comment on our estimate of the time required to nominate an MVP. We did not receive comments related to the estimate of time required to nominate an MVP.

Similar to the call for quality measures, nomination of Promoting Interoperability measures, and the nomination of improvement activities, we assume MVP nomination will be performed by both practice administration staff or their equivalents and clinicians. We estimate 7.2 hours at $110.74/hr for a medical and health services manager or equivalent and 4.8 hours at $212.78/hr for a physician to nominate an MVP. As shown in Table 93, we estimate an annual burden of 300 hours (25 nominations × 12 hr/nomination) at a cost of $45,467 (25 × [(7.2 hr × $110.74/hr) + (4.8 hr × $212.78/hr)]).

TABLE 93: Estimated Burden for Nomination of MVPs

	Burden Estimate
# of Nominations of New Improvement Activities (a)	25
# of Hours Per Medical and Health Services Manager (b)	7.2
# of Hours Per Physician (c)	4.8
Annual Hours Per Respondent (d)= (b) + (c)	12
Total Annual Hours (e) = (a)*(d)	**300**
Cost to Nominate an MVP (@ medical and health services manager's labor rate of $110.74/hr) (f)	$797.33
Cost to Nominate an MVP (@ physician's labor rate of $212.78/hr) (g)	$1,021.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$1,818.67
Total Annual Cost (i)=(a)*(h)	**$45,467**

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the provisions of this final rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not setting out burden or making any changes under the 0938–1197 control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule did not propose any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we are adjusting our currently approved burden estimates based on updated projections for the 2021 MIPS performance period. The burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As shown in Table 94, based on our predictive QP analysis for the 2021 QP performance period, which accounts for historical response rates in performance year 2019, we estimate that 100 APM Entities and 200 eligible clinicians (representing approximately 2,500 Partial QPs) will make the election to participate as a Partial QP in MIPS, a total of 300 elections which is a decrease of 1,722 from the 2,022 elections that are currently approved by OMB under the aforementioned control number. We continue to estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate an annual burden of 75 hours (300 respondents × 0.25 hr/election) and $6,935 (75 hr × $92.46/hr).

TABLE 94: Estimated Burden for Partial QP Election

	Burden Estimate
# of respondents making Partial QP election (100 APM Entities, 200 eligible clinicians) (a)	300
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a)*(b)	**75**
Labor rate for computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$6,935**

As shown in Table 95, using our unchanged currently approved per respondent burden estimate, the decrease in the number of Partial QP elections results in an adjustment of −430.5 hours (−1,722 elections × 0.25 hr) from our currently approved burden of 505.5 hours at a cost of −$39,804 (−430.5 hr × $92.46/hr) (84 FR 63142).

TABLE 95: Adjusted Burden for Partial QP Election

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	505.5
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	75
Difference (c) = (b)-(a)	**-430.5**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$46,739
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$6,935
Difference (f) = (e)-(d)	**-$39,804**

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician Initiated Process (§ 414.1445)

The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1445)

This rule is not implementing any new or revised collection of information requirements related to the Payer-Initiated Process. However, we are adjusting our currently approved burden estimates based on updated projections for the 2021 MIPS performance period. As mentioned above, the adjusted burden will be submitted to OMB for approval.

As shown in Table 96, based on the actual number of requests received in the 2019 QP performance period, we estimate that in CY 2021 for the 2022 QP performance period 80 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 20 remaining other payers), a decrease of 30 from the 110 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We estimate an annual burden of 800 hours (80 submissions × 10 hr/submission) and $73,968 (800 hr × $92.46/hr).

TABLE 96: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
# of other payer payment arrangements (10 Medicaid, 50 Medicare Advantage Organizations, 20 remaining other payers) (a)	80
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	**800**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$73,968**

As shown in Table 97, using our unchanged currently approved per respondent burden estimate, the decrease in the number of payer-initiated requests from 110 to 80 results in an adjustment of −300 hours (−30 requests × 10 hr) from our currently approved burden of 1,100 hours at a cost of −$27,738 (−300 hr × $92.46/hr) (84 FR 63143).

TABLE 97: Adjusted Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	1,100
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	800
Difference (c) = (b)-(a)	**-300**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$101,706
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$73,968
Difference (f) = (e)-(d)	**-$27,738**

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule is not implementing any new or revised collection of information requirements or burden related to the Eligible-Clinician Initiated Process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the eligible clinician initiated process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule is not implementing any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the QP Determinations under the All-Payer Combination Option under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule is not implementing any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we are adjusting our currently approved burden estimates based on data from the 2019 MIPS performance period. The burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53924 through 53925), CY 2019 PFS final rule (83 FR 60022), and the CY 2020 PFS final rule (84 FR 63145 through 63146) for our previously finalized requirements and burden for voluntary participants to opt-out of public reporting on Physician Compare.

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 3,486 (0.10 × 34,860 voluntary MIPS participants) clinicians and groups, a decrease of −6,556 from the currently approved estimate of 10,042 and a decrease of 6,418 from the estimate of 9,904 provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50367). Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the RIA section of the CY 2019 PFS final rule, we estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

Table 98 shows that for these voluntary participants, we continue to estimate it will take 0.25 hours for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 871.5 hours (3,486 requests × 0.25 hr/request) and $80,579 (871.5 hr × $92.46/hr).

TABLE 98: Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	3,486
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours (c) = (a)*(b)	**871.5**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	**$80,579**

As shown in Table 99, using our unchanged currently approved per respondent burden estimate, the decrease of −6,556 opt outs by voluntary participants results in an adjustment of −1,639 hours (−6,556 requests × 0.25 hr) at a cost of −$151,542 (−1,639 hr × $92.46/hr).

TABLE 99: Adjusted Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	2,510.5
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	871.5
Difference (c) = (b)-(a)	**-1,639**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$232,121
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$80,579
Difference (f) = (e)-(d)	**-$151,542**

p. Summary of Annual Quality Payment Program Burden Estimates

Table 100 summarizes this final rule's burden estimates for the Quality Payment Program for both the 2021 and 2022 performance periods. In the CY 2020 PFS final rule, the total estimated burden was 2,932,649 hours at a cost of $279,550,490 ($279,573,747—$23,257) (84 FR 63146). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2020 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2020 PFS final rule into the 2021 and 2022 MIPS performance periods is 2,938,128 hours at a cost of $287,216,853; an increase of 5,479 hours and $7,666,363. To understand the burden implications of the policies in this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2020 PFS final rule into the 2021 and 2022 MIPS performance periods. This burden estimate of 1,478,504 hours at a cost of $144,456,084 reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflect the exclusion of QPs from all MIPS performance categories, a difference of −1,459,624 hours and −$142,760,769. This burden estimate is lower than the burden approved for information collection related to the CY 2020 PFS final rule due to updated data and assumptions as well as the addition of the Open Authorization Credentialing and Token Request Process information collection, which is not a result of any new or revised policies in this rule or finalized in any previous final rule, but rather an operational improvement. The difference of −4,763 hours (1,459,624 hours −1,462,534 hours −1,854 hours) and −$421,117 ($142,760,769 −$143,134,204 −$47,681) between this estimate and the total burden shown in Table 103 is the reduction in burden associated with impacts of the policy to sunset the CMS Web Interface measures as a collection type/submission type; partially offset by an increase in burden due to a new information collection for nomination of MVPs, the policies to require QCDRs and qualified registries to conduct targeted audits as necessary, the policy to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the CAHPS for MIPS Survey, the policy to allow APM Entities to submit an extreme and uncontrollable circumstances exception application, and the policy to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible. We have included Table 100 to assist in understanding these differences. Note that the difference between the burden estimates for the 2021 and 2022 MIPS performance periods is entirely due to the finalized policy to sunset the CMS Web Interface measures as a collection type/submission type beginning in the 2022 MIPS performance period.

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TABLE 100: Summary of Changes in Burden from the CY 2020 PFS Final Rule

2021 MIPS Performance Period		
Burden Estimate Description	**Burden Hours**	**Burden Cost**
CY 2020 PFS Final Rule (a)	2,932,649	$279,550,490
CY 2021 PFS Final Rule w/ updated wage rates and ICRs (b)	2,938,128	$287,216,853
CY 2021 PFS Final Rule w/ updated data and assumptions (c)	1,478,509	$144,456,570
Change in burden due to updated data and assumptions (d) = (c) – (b)	**-1,459,619**	**-$142,760,284**
CY 2021 PFS Final Rule Total Burden (e)	1,479,672	$144,576,960
Total change in burden (f) = (e) – (b)	**-1,458,457**	**-$142,639,893**
Change in burden associated with policies (g) = (f) – (d)	**+1,163**	**+$120,391**
2022 MIPS Performance Period		
Burden Estimate Description	**Burden Hours**	**Burden Cost**
CY 2020 PFS Final Rule (h)	2,932,649	$279,550,490
CY 2021 PFS Final Rule w/ updated wage rates and ICRs (i)	2,938,128	$287,216,853
CY 2021 PFS Final Rule w/ updated data and assumptions (j)	1,478,504	$144,456,084
Change in burden due to updated data and assumptions (k) = (j) – (i)	**-1,459,624**	**-$142,760,769**
CY 2021 PFS Final Rule Total Burden (l)	1,473,741	$144,034,968
Total change in burden (as shown in Table 103) (m) = (l) – (i)	**-1,464,388**	**-$143,181,886**
Change in burden associated with policies (n) = (m) – (k)	**-4,763**	**-$421,117**

TABLE 101: Summary of Quality Payment Program Burden Estimates and Requirements

Requirement	Currently Approved Responses*	Finalized Responses	Change in Responses	Currently Approved Total Burden Hours*	Finalized Total Burden Hours	Change in Total Burden Hours
§ 414.1400 QCDR self-nomination (see section VII.B.5.c.(2))*	76	82	+6	608	826	+218
§ 414.1400 Registry self-nomination (see section VII.B.5.c.(3))*	153	193	+40	459	1,139	+680
Open Authorization Credentialing and Token Request Process (see section VII.B.5.d)	0	15	+15	0	15	+15
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section VII.B.5.e.(4))	94,846	29,273	-65,573	1,346,813	415,677	-931,137
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section VII.B.5.e.(5)): 2021 Performance Period	111,218	52,899	-58,319	1,010,193	480,482	-529,711
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section VII.B.5.e.(5)): 2022 Performance Period	111,218	52,949	-58,269	1,010,193	480,890	-529,711
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section VII.B.5.e.(6)): 2021 Performance Period	43,333	50,409	+7,076	346,664	403,272	+56,608
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section VII.B.5.e.(6)): 2022 Performance Period	43,333	50,470	+7,137	346,664	403,800	+57,136
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section VII.B.5.e.(7)): 2021 Performance Period	104	111	+7	6,414	6,845	+431
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section VII.B.5.e.(7)): 2022 Performance Period	104	0	-104	6,414	0	-6,414
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section VII.B.5.e.(9)): 2021 Performance Period	69	90	+21	17.25	22.5	+5.25
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section VII.B.5.e.(9)): 2022 Performance Period	69	0	-69	17.25	0	-17.25
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section VII.B.5.g.(2))	30,620	52,099	+21,479	7,655	13,025	+5,370
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section VII.B.5.g.(3))	74,281	53,636	-20,645	198,083	143,029	-55,054
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section VII.B.5.i	103,813	79,927	-23,886	8,651	6,661	-1,990
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see section VII.B.5.j	31	31	0	62	93	+31
Nomination of MVPs (see section VII.B.5.k)	0	25	+25	0	300	+300
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section VII.B.5.m)	2,022	300	-1,722	505.5	75	-430.5
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	110	80	-30	1,100	800	-300

Requirement	Currently Approved Responses*	Finalized Responses	Change in Responses	Currently Approved Total Burden Hours*	Finalized Total Burden Hours	Change in Total Burden Hours
(see section VII.B.5.n.(1)						
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see section VII.B.5.o	10,042	3,486	-6,556	2,510.5	871.5	-1,639
SUBTOTAL OMB 0938-1314 (CMS-10621): 2021 Performance Period	**470,718**	**322,656**	**-148,062**	**2,929,735**	**1,473,132**	**-1,456,603**
SUBTOTAL OMB 0938-1314 (CMS-10621): 2022 Performance Period	**470,718**	**322,566**	**-148,152**	**2,929,735**	**1,467,201**	**-1,462,534**
§§ 414.1325 and 414.1335 Beneficiary Responses to CAHPS for MIPS Survey (see section VII.B.5.e.(8))	39,039	29,952	-9,087	8,393	6,540	-1,854
SUBTOTAL OMB 0938-1222 (CMS-10450): 2021 and 2022 Performance Periods	**39,039**	**29,952**	**-9,087**	**8,393**	**6,540**	**-1,854**
TOTAL: 2021 Performance Period	**509,757**	**352,608**	**-157,149**	**2,938,128**	**1,479,672**	**-1,458,457**
TOTAL: 2022 Performance Period	**509,757**	**352,518**	**-157,239**	**2,938,128**	**1,473,741**	**-1,464,388**

*Total Responses is equal to the number of self-nomination applications plus the number of Corrective Action Plans submitted.

Table 102 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this final rule. We have divided the reasons for our change in burden into those related to new policies and those related to adjustments in burden from continued Quality Payment Program Year 4 policies that reflect updated data and revised methods.

TABLE 102: Reasons for Change in Burden Compared to the Currently Approved CY 2020 Information Collection Burden

Quality Payment Program Table	Changes in burden due to CY 2021 Final Rule policies	Adjustments in burden from continued CY 2020 Final Rule policies due to revised methods or updated data
Section VII.B.5.c.(2): QCDR Self-Nomination and other Requirements	Increase in burden due to policy requiring targeted audits, as necessary (+5 to +10 hours per audit).	Increase in number of respondents due to use of updated data from the 2020 MIPS performance period.
Section VII.B.5.c.(3): Qualified Registry Self-Nomination and other Requirements	Increase in number of responses (+10) and burden (+ 3 hrs per response) due to current policies not previously having a burden estimate as well as the provision to require additional information in Corrective Action Plans. Increase in burden due to policy requiring targeted audits, as necessary (+5 to +10 hours per audit).	Increase in number of respondents due to use of updated data from the 2020 MIPS performance period.
Section VII.B.5.d: Open Authorization Credentialing and Token Request Process	New information collection request.	Not applicable.
Section VII.B.5.e.(4): Quality Performance Category Medicare Part B Claims Collection Type	None.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.e.(5): Quality Performance Category QCDR/ MIPS CQM Collection Type	(2022 Performance Period) Increase in number of respondents (+7) due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.e.(6): Quality Performance Category eCQM Collection Type	(2022 Performance Period) Increase in number of respondents due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	Increase in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.e.(7): Quality Performance Category CMS Web Interface Collection Type	(2022 Performance Period) Removal of information collection due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	(2021 Performance Period) Increase in number of respondents due to use of updated data from the 2019 MIPS performance period.
Section VII.B.5.e.(8): Beneficiary Responses to CAHPS for MIPS Survey	Increase in per response burden (+ 0.2 hrs) due to the provision to add a survey-based measure on telehealth.	Decrease in number of respondents due to updated data from 2019 MIPS performance period.
Section VII.B.5.e.(9): Registration for CMS Web Interface	(2022 Performance Period) Removal of information collection due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	(2021 Performance Period) Increase in number of respondents due to use of updated data from the 2020 MIPS performance period.
Section VII.B.5.g.(2): Reweighting Applications for Promoting Interoperability and Other Performance Categories	Increase in number of respondents due to the provision to allow APM Entities to submit an extreme and uncontrollable circumstances exception application.	Increase in number of applications submitted due to updated data from the 2019 MIPS performance period.

Quality Payment Program Table	Changes in burden due to CY 2021 Final Rule policies	Adjustments in burden from continued CY 2020 Final Rule policies due to revised methods or updated data
Section VII.B.5.g.(3): Promoting Interoperability Performance Category Data Submission	None.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.i: Improvement Activities Submission	None.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period.
Section VII.B.5.j: Nomination of Improvement Activities	Increase in per response burden (+1 hour) due to the provision to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible.	None.
Section VII.B.5.k: Nomination of MVPs	New information collection request.	Not applicable.
Section VII.B.5.m: Partial QP Election	None	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Section VII.B.5.n.(1): Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Section VII.B.5.o: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to use of updated data from the 2019 MIPS performance period.

C. Summary of Annual Burden Estimates for Requirements

TABLE 103: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 424.67 (Conditions for Payment, Form CMS-855A)	0938-0685	133	133	varies	532	varies	23,598
§ 424.67 (Conditions for Payment, Form CMS-855B)	0938-1377	23	23	varies	-89	varies	-4,091
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan)	0938-TBD	148,750	560,430	5	743,750	36.62	27,236,125
§§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)	0938-1314	123,619	-148,152	varies	1,462,534	varies	143,134,204
§§ 414.1325 and 414.1335 (Quality Payment Program)	0938-1222	29,952	-9,087	0.22	-1,854	25.72	-47,681
TOTAL		302,477	403,347	varies	2,204,873	varies	$170,342,155

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VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule would make payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, the Bipartisan Budget Act of 2018, and sections 2005, 6063, and 6111 of the SUPPORT for Patients and Communities Act of 2018. This final rule would also make changes to payment policy and other related policies for Medicare Part B.

This final rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we included a detailed Regulatory Impact Analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to statutory requirements and, to the extent feasible, maximize net benefits.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this final rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this final rule does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. This final rule is expected to be an E.O. 13771 regulatory action. We estimate the rule generates $1.23 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule, we discussed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant federal

rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2020 with payment rates for CY 2021 using CY 2019 Medicare utilization. The payment impacts in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2021, as required by section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments.

To calculate the CY 2021 PFS conversion factor (CF), we multiplied the product of the current year CF and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimate the CY 2021 PFS CF to be 32.4085 which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act. We estimate the CY 2021 anesthesia CF to be 20.0547 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 104: Calculation of the CY 2021 PFS Conversion Factor

CY 2020 Conversion Factor		36.0896
Statutory Update Factor	0.00 percent (1.0000)	
CY 2021 RVU Budget Neutrality Adjustment	-10.20 percent (0.8980)	
CY 2021 Conversion Factor		**32.4085**

TABLE 105: Calculation of the CY 2021 Anesthesia Conversion Factor

CY 2020 National Average Anesthesia Conversion Factor		22.2016
Statutory Update Factor	0.00 percent (1.0000)	
CY 2021 RVU Budget Neutrality Adjustment	-10.20 percent (0.8980)	
CY 2021 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.59 percent (1.0059)	
CY 2021 Conversion Factor		**20.0547**

Table 106 shows the payment impact on PFS services of the policies contained final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 106 (CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 106.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2019 utilization and CY 2020 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2021 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2021 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2021 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2021 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 106: CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
ALLERGY/IMMUNOLOGY	$247	5%	4%	0%	9%
ANESTHESIOLOGY	$2,020	-6%	-1%	0%	-8%
AUDIOLOGIST	$75	-4%	-2%	0%	-6%
CARDIAC SURGERY	$266	-5%	-2%	0%	-8%
CARDIOLOGY	$6,871	1%	0%	0%	1%
CHIROPRACTOR	$765	-7%	-3%	0%	-10%
CLINICAL PSYCHOLOGIST	$832	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	$857	0%	1%	0%	1%
COLON AND RECTAL SURGERY	$168	-4%	-1%	0%	-5%
CRITICAL CARE	$378	-6%	-1%	0%	-7%
DERMATOLOGY	$3,767	-1%	0%	0%	-1%
DIAGNOSTIC TESTING FACILITY	$748	-1%	-2%	0%	-3%
EMERGENCY MEDICINE	$3,077	-5%	-1%	0%	-6%
ENDOCRINOLOGY	$508	10%	5%	1%	16%
FAMILY PRACTICE	$6,020	8%	4%	0%	13%
GASTROENTEROLOGY	$1,757	-3%	-1%	0%	-4%
GENERAL PRACTICE	$412	5%	2%	0%	7%
GENERAL SURGERY	$2,057	-4%	-2%	0%	-6%
GERIATRICS	$192	1%	1%	0%	3%
HAND SURGERY	$246	-2%	-1%	0%	-3%
HEMATOLOGY/ONCOLOGY	$1,707	8%	5%	1%	14%
INDEPENDENT LABORATORY	$645	-3%	-2%	0%	-5%
INFECTIOUS DISEASE	$656	-4%	-1%	0%	-4%
INTERNAL MEDICINE	$10,730	2%	1%	0%	4%
INTERVENTIONAL PAIN MGMT	$936	3%	3%	0%	7%
INTERVENTIONAL RADIOLOGY	$499	-3%	-5%	0%	-8%
MULTISPECIALTY CLINIC/OTHER PHYS	$153	-3%	-1%	0%	-3%
NEPHROLOGY	$2,225	4%	2%	0%	6%
NEUROLOGY	$1,522	3%	2%	0%	6%
NEUROSURGERY	$811	-4%	-2%	-1%	-6%
NUCLEAR MEDICINE	$56	-5%	-3%	0%	-8%
NURSE ANES / ANES ASST	$1,321	-9%	-1%	0%	-10%
NURSE PRACTITIONER	$5,100	5%	3%	0%	7%
OBSTETRICS/GYNECOLOGY	$636	4%	3%	0%	7%
OPHTHALMOLOGY	$5,343	-4%	-2%	0%	-6%
OPTOMETRY	$1,359	-2%	-2%	0%	-4%
ORAL/MAXILLOFACIAL SURGERY	$79	-2%	-2%	0%	-4%
ORTHOPEDIC SURGERY	$3,812	-3%	-1%	0%	-4%
OTHER	$48	-3%	-2%	0%	-5%
OTOLARNGOLOGY	$1,271	4%	3%	0%	7%
PATHOLOGY	$1,265	-5%	-4%	0%	-9%
PEDIATRICS	$67	4%	2%	0%	6%
PHYSICAL MEDICINE	$1,164	-3%	0%	0%	-3%
PHYSICAL/OCCUPATIONAL THERAPY	$4,973	-4%	-4%	0%	-9%
PHYSICIAN ASSISTANT	$2,901	5%	2%	0%	8%
PLASTIC SURGERY	$382	-4%	-3%	0%	-7%
PODIATRY	$2,133	-1%	0%	0%	-1%
PORTABLE X-RAY SUPPLIER	$95	-2%	-4%	0%	-6%
PSYCHIATRY	$1,112	4%	3%	0%	7%
PULMONARY DISEASE	$1,654	0%	0%	0%	1%
RADIATION ONCOLOGY AND RADIATION	$1,809	-3%	-3%	0%	-5%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
THERAPY CENTERS					
RADIOLOGY	$5,275	-6%	-4%	0%	-10%
RHEUMATOLOGY	$548	10%	5%	1%	15%
THORACIC SURGERY	$352	-5%	-2%	0%	-8%
UROLOGY	$1,810	4%	4%	0%	8%
VASCULAR SURGERY	$1,293	-2%	-4%	0%	-6%
TOTAL	**$97,008**	**0%**	**0%**	**0%**	**0%**

* Column F may not equal the sum of columns C, D, and E due to rounding.

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2. CY 2021 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including endocrinology, rheumatology, family practice, and hematology/oncology reflect increases relative to other physician specialties. These increases can largely be attributed to previously finalized policies for increases in valuation for office/outpatient E/M visits which constitute nearly 20 percent of total spending under the PFS. These increases are also due to increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC) and CMS review, increased payments as a result of finalized updates to supply and equipment pricing, and the continuing implementation of the adjustment to indirect PE allocation for some office-based services. For nephrologists, the increase in the valuations of the ESRD monthly capitation payments that have office/outpatient E/M visits explicitly included in their valuations result in estimated impacts of +6 percent. For clinical social workers and clinical psychologists, to the increase in the valuations for certain behavioral health services that are analogous to office/outpatient E/M visits result in estimated impacts of 0 to 1 percent.

The estimated impacts for several specialties, including radiology, nurse anesthetists, pathology, and cardiac surgery reflect decreases in payments relative to payment to other physician specialties which are largely the result of the redistributive effects of previously finalized changes to the office/outpatient E/M visits taking effect in 2021. These decreases are also due to the revaluation of individual procedures reviewed by the AMA's RUC and CMS, as well as decreased payments as a result of continuing implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For the physical/occupational therapy specialty, estimated impacts of -9 percent reflect increased valuations for therapy evaluation services that are analogous to office/outpatient E/M visits. However, therapy evaluation services do not account for a large portion of allowed charges for these specialties.

For emergency medicine practitioners, estimated impacts of -6 percent reflect a 2 percent gain as a result of increased valuations to emergency department visits using specialty society recommendations to maintain relativity with office/outpatient E/M visits. However, the magnitude of the office/outpatient E/M visit valuations are dampening the effect of increased valuations for the emergency department (ED) visits. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 5 percent decrease for CY 2021 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 106), including comments received in response to the rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in Table 106 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 106 displays the estimated CY 2021 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2021 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

We received public comments about the impacts of this provision. The following is a summary of the comments we received and our response.

Comment: In general, commenters from physician specialties who saw projected increases related to our previously finalized revaluation of the office/outpatient E/M code set, our implementation of HCPCS code G2211, and our revaluations of services analogous to office/outpatient E/Ms

were supportive, while those commenters from physician specialties who projected decreases objected. Many commenters expressed concern with the budget neutrality adjustments associated with implementing our previously finalized revaluation of the office/outpatient E/M codes, particularly for those specialties who do not bill for office/outpatient E/M visits.

Response: While we understand the concerns articulated by commenters, our approach to making the required budget neutrality adjustment to account for changes in expenditures resulting from changes to RVUs, including those for the office/outpatient E/M code set and other similar services, is consistent with the approach we have applied to achieve budget neutrality in the past in accordance with the requirements of the statute. The statutory waiver authorities available to the Secretary following a public health emergency declaration, which are largely established in section 1135 of the Act, do not include waiver authority that would allow for implementation of changes to the PFS outside of the budget neutrality requirements in statute. The changes we make to RVUs are directed at setting appropriate resource-based relative values in accordance with section 1848 of the Act, and any increases or decreases in estimated payments associated with our finalized policies are purely a result of our longstanding budget neutrality process.

Comment: Several commenters suggested that the Secretary use waiver authority in response to the PHE for COVID–19 to implement the revaluations to the office/outpatient E/M visits, analogous services, and HCPCS code G2211 without application of the budget neutrality adjustment. Several other commenters requested that CMS exempt specialties that do not predominantly bill for office/outpatient E/M services from the budget neutrality adjustment.

Response: While we understand the concerns articulated by the commenters, we reiterate that section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality. The Secretary's waiver authority pursuant to the public health emergency declaration for COVID–19 does not extend to authorize changes to the PFS outside of budget neutrality. Additionally, section 1848 of the Act does not grant the Secretary the authority to exempt categories of physicians or practitioners from the budget neutrality adjustments.

Comment: Some commenters requested that CMS provide additional analysis on the potential impact of our finalized policies on small businesses.

Response: We appreciate the interest from commenters and the request that we provide additional analysis on the potential impact of our finalized policies on small businesses. Our discussion of the potential impacts complies with RFA requirements regarding significant impact on a substantial number of small entities. Our longstanding policy for our impacts discussion is to provide analysis at the level of certain specialties, as identified in the specialty information captured in our Medicare provider enrollment files. We would note that the lack of granular, national and publicly available data that could be used to identify variability between localities, business types, and the specific mixture of Medicare/non-Medicare payment for a given business makes it difficult to project impacts on small businesses using our standard process.

D. Effect of Changes Related to Telehealth Services

As discussed in section II.F. of this final rule, we are adding nine new codes to the list of Medicare telehealth services list for CY 2021. These codes are:

- Group Psychotherapy (CPT 90853)
- Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99334–99335)
- Home Visits, Established Patient (CPT 99347–99348)
- Cognitive Assessment and Care Planning Services (CPT 99483)
- Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS G2211)
- Prolonged Services (HCPCS G2212)
- Psychological and Neuropsychological Testing (CPT 96121)

We are also adding the following services to the list of Medicare telehealth services provisionally on a category 3 basis:

- Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99336–99337)
- Home Visits, Established Patient (CPT 99349–99350)
- Emergency Department Visits, Levels 1–5 (CPT 99281–99285)
- Nursing facilities discharge day management (CPT 99315–99316)
- Psychological and Neuropsychological Testing (CPT 96130–96133; CPT 96136–96139)
- Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161–97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521–92524, 92507)
- Hospital discharge day management (CPT 99238–99239)
- Inpatient Neonatal and Pediatric Critical Care, Subsequent (CPT 99469, 99472, 99476)
- Continuing Neonatal Intensive Care Services (CPT 99478–99480)
- Critical Care Services (CPT 99291–99292)
- End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962)
- Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224–99226)

Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, services already on the list of permanent telehealth services are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. The statutory payment requirements for Medicare telehealth services under section 1834(m) of the Act, such as the originating site requirements related to geographic location and site of service, limit increases in utilization outside of the PHE for the COVID–19 pandemic; however, we believe there is value in allowing physicians to furnish these additional services via telehealth, and for patients to receive broader access to this care through telehealth. Additionally, for services added to the Medicare telehealth list on a Category 3 basis, outside of the circumstances of the PHE for COVID–19, all of the statutory restrictions will also apply to these services. Even with the addition of the category 3 services for an additional year, we do not anticipate any significant increase in utilization after the PHE for COVID-ends. We note that due to flexibilities implemented during the PHE for the COVID–19 pandemic, particularly waivers of the statutory geographic and site-of-service restrictions, has led to increased utilization of telehealth services; [149]

[149] *https://aspe.hhs.gov/pdf-report/medicare-beneficiary-use-telehealth, https://aspe.hhs.gov/system/files/pdf/264071/Medicare-FFS-Spending-Utilization.pdf.*

however, we do not believe we have sufficient data to draw any further conclusions. CMS will need to conduct additional analyses once there are sufficient data such as a full year's worth of claims that will allow us to consider the effects of the PHE on utilization in the context of the annual/seasonal variations observed in the claims data that exist from one year to the next. Such analysis would inform CMS options for adopting any flexibilities on a permanent basis, as allowed by Medicare statute outside of the circumstances of the PHE. This information would also be taken into consideration for future ratesetting under the PFS.

E. Effect of Changes Related to Scopes of Practice

As discussed in section II.G. Scopes of Practice for PFS Services, of this final rule, we will allow certain NPPs to supervise diagnostic tests, which would authorize NPs, CNSs, PAs, CNMs, and CRNAs to provide the appropriate level of supervision assigned to diagnostic tests, to the extent authorized under State law and scope of practice. As for all services they furnish, in accordance with statute, the NP, CNS or PA necessarily would be working either under physician supervision or in collaboration with a physician. This flexibility may increase the capacity and availability of practitioners who can supervise diagnostic tests, which would alleviate some of the demand on physicians as the only source to perform this particular function.

We solicited comment on state scope of practice rules and they extent to which they specified supervision requirements for the supervision of diagnostic tests. Some commenters provided information on specific tests and thoughts on what practitioners could supervise such tests, these commenters provided information indicating that psychological and neuropsychological diagnostic tests are not within the scope of practice of the proposed NPPs, and require special training only available to psychologists and physicians. While this information provides some context to our policy discussion, overall, we have not located national detailed information indicating the degree to which NPP scope of practice includes supervision of auxiliary staff, especially for the subset of services that are diagnostic tests and note that here is a wide range of diagnostic tests, from a simple strep throat swab to more sophisticated and/or invasive tests such as X-rays and cardiology procedures. We would need to understand the scope of practice for many types of auxiliary staff (some of whom are not licensed) who could potentially provide these tests under the supervision of an NPP, including RNs, LPNs, medical assistants, radiologic technicians, and many others. However, as discussed earlier in this rule, our intent regarding this supervision flexibility is to allow NPPs with separate benefit categories under Medicare law to supervise the performance of diagnostic tests, regardless of the specific category of diagnostic tests, only to the extent their scope of practice and State laws authorize them to do so.

To the extent practice patterns change, there could be induced utilization that would increase costs, but this might be offset by reduced payment rates because direct payment to NPPs is at a lower rate than payment to physicians.

An alternative in the case of the provision concerning supervision of diagnostic tests was to maintain the status quo. That is, we noted that we could maintain the basic rule under § 410.32(b)(1) that allows only physicians as defined under Medicare law to supervise the performance of diagnostic tests. In that case, the pool of practitioners who could supervise diagnostic tests would remain at current levels and certain NPPs would be limited under Medicare from practicing to the full extent allowed by their state license and scope of practice.

We are finalizing the proposal to allow a physical therapist (PT) or occupational therapist (OT)—whether they are an enrolled private practice PT or OT or a therapist working for an institutional provider—who establishes a therapy maintenance program to assign the duties to a PTA or OTA, as clinically appropriate, to perform maintenance therapy services. We added this as a flexibility under the May 8th COVID–19 IFC for the duration of the PHE for COVID–19 based on respondents' feedback on scope of practice following the President's E.O. 13890. Our current requirements for maintenance therapy services restrict a PT's/OT's ability to delegate the performance of maintenance therapy services to PTAs and OTAs which is counter to the therapist's ability to use PTAs/OTAs in furnishing rehabilitative outpatient physical or occupational therapy services. In the CY 2021 PFS proposed rule (85 FR 50147), we proposed to allow PTs/OTs to oversee and delegate to a PTA or OTA the performance of physical and occupational therapy services in the same way, whether the therapy services are part of a plan of care geared toward rehabilitative or maintenance therapy. While therapy services furnished by PTs/OTs and their PTAs/OTAs are separately payable when they occur in different time slots (that is, if the PT/PTA or OT/OTA work together at the same time in furnishing a service to the patient, only one service is payable), we noted that we did not believe that there would be an increase in utilization since it is of no consequence whether the PTA/OTA is furnishing the service as rehabilitative or maintenance therapy. Additionally, we note that beginning January 1, 2022, payment for services furnished in whole or in part by a PTA/OTA (when the part by the PTA/OTA separate from the part of furnished by the PT/OT exceeds 10 percent of the service) will be paid at a lower rate (85 percent of the PFS fee schedule amount) which could offset any nominal increase in service volume. The alternative option—maintaining the status quo to require the PT/OT to personally furnish all maintenance therapy services, would not address the mandates established in E.O. 13890. Currently, in SNF and home health settings when payment for therapy is made under Part A, maintenance therapy can be furnished by a PT/OT or delegated to be performed by a PTA/OTA, and this provision would permit this to occur in all settings when therapy is paid under Part B.

F. Effect of Changes to Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

As discussed in section II.H. of this final rule, Valuation of Specific Codes, we are expanding the bundled payments described by HCPCS codes G2086, G2087, and G2088, finalized in the CY 2020 PFS final rule (84 FR 62673) to be inclusive of all SUDs. As noted in the CY 2020 PFS final rule (84 FR 62673), if a patient's treatment involves MAT, this bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged. We note that payment for the codes would be budget neutral under the PFS and therefore have no cost impact on PFS spending; however, this policy may have impacts on billing practices and services provided.

Currently, the codes most frequently used when billing for treatment of SUD include the E/M visit codes, psychotherapy codes, SBIRT codes, and potentially the Behavioral Health Integration codes. HCPCS codes G2086–G2088 offer a bundled payment that would allow a more streamlined

approach to billing in cases where all of the services described in the code descriptors are furnished. We note that these codes provide an option for billing, but are not required; therefore, in cases where only select services are being furnished, practitioners may continue to bill for the code that most accurately describes the service that was furnished, which could be, for example, an E/M visit code.

G. Effect of Modifications to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Section 2005 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit for OUD treatment services furnished by OTPs on or after January 1, 2020. As part of CY 2020 PFS rulemaking, we implemented coverage requirements, created new coding to describe bundled episodes of care for the treatment of OUD, and established payment methodologies to determine the payment amounts for the drug and non-drug components of an episode of care.

For CY 2021, we are creating two new add-on codes, one add-on code for nasal naloxone and another add-on code for injectable naloxone. Both add-on codes include a non-drug component for overdose education furnished in conjunction with naloxone. We are pricing nasal naloxone based upon the methodology set forth in section 1847A of the Act, except that the payment amount shall be ASP + 0. The price being finalized for the nasal naloxone add-on code is $92.13, which includes a payment of $2.53 for overdose education. We are contractor-pricing the injectable naloxone and will also include a payment of $2.53 for overdose education. We are limiting Medicare payment to OTPs for naloxone to one add-on code (HCPCS code G2215 or G2216) every 30 days, however, we will allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of naloxone dispensed by the OTP, to the extent that it is medically reasonable and necessary to furnish additional naloxone.

The estimated net Part B cost impact of the add-on codes for naloxone for CY 2021 is $0.5 million. The estimated net Part B 10-year impact is $5.6 million. This estimate is based on several assumptions. First, commenters noted that nasal naloxone is the most common formulation given to patients in an OTP and the price is being finalized is $92.13. This cost is to be updated to reflect changes in the average sales price (ASP); however, since future ASP updates are not available, the Medicare Economic Index (MEI) was used as a proxy. Based on partial 2020 utilization of the OTP benefit through September, roughly 20,000 beneficiaries received treatment at an OTP at some point during that time. We assumed that this would reach 25,000 by the end of 2020, and growth in future years would be consistent with projected growth in Part B fee-for-service enrollment. We assumed that beneficiaries who are provided naloxone would receive at least one supply of nasal naloxone as a standard part of the program because they are likely to be at risk for an overdose. A much smaller portion would receive a second supply, since it would only be provided if the first supply has been used. We assumed that approximately 1.1 doses would be provided per beneficiary. This figure is based on an August 2020 OIG report regarding opioid use under Medicare Part D, and it represents the average number of prescriptions per person receiving naloxone between 2016 and 2019 (see Exhibit B–2 on page 14).[150] We assumed that roughly 25 percent of beneficiaries receiving treatment OTPs would be provided with naloxone, because they may already have it from another source, and some OTPs may not have it available. The estimate also took into account that this benefit is not subject to beneficiary cost sharing. Additionally, any change to FFS benefits has an associated impact on payments to Medicare Advantage (MA) plans, so an adjustment was made to reflect this based on the projected distribution of spending in each year. Based on current projections, payments to MA plans represent roughly 46 percent of total Part B spending in 2022 this share and is expected to grow to almost 50 percent by 2030. This estimate also takes into account a premium offset which represents the impact on the Medicare program due to the change in the Part B premium as a result of the new add-on payment to OTPs for naloxone. In other words, since benefit spending is higher, the Part B premium will also be higher, which partially offsets the impact on benefit spending. The Part B FFS enrollment projections and MEI assumptions are based on the President's Fiscal Year 2021 Budget baseline that was released in February of 2020.

We believe that the benefits associated with establishing payment for naloxone and overdose education in the OTP setting justify the cost of the provision. As noted in section II.I. of this final rule, Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs), U.S. Surgeon General Jerome M. Adams, M.D., M.P.H. released a public health advisory stating that, ''Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities. Therefore, increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.'' [151] We are adding naloxone and overdose education furnished in conjunction with naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and to allow OTPs to be paid under Medicare for dispensing naloxone to Medicare beneficiaries who are receiving other OUD treatment services from the OTP. We believe allowing beneficiaries to access this important emergency treatment at the OTP may help decrease barriers to access because there are no copayments for services furnished by OTPs and beneficiaries will not need to visit a separate provider to access naloxone.

H. Other Provisions of the Regulation

1. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

In section III.A. of this final rule, we discuss statutory revisions to the data reporting period and phase-in of payment reductions. In accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we are making certain conforming changes to the data reporting and payment requirements in our regulations at part 414, subpart G. Specifically, for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), we are revising § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. This revision delays the next data reporting period under the CLFS by 2 years, that is, it will require the next data reporting during the period of January 1, 2022 through March 31, 2022. Subsequently, the next private payor

[150] *https://oig.hhs.gov/oei/reports/OEI-02-20-00320.pdf.*

[151] *https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.*

rate-based CLFS update will be effective January 1, 2023 instead of January 1, 2021. In addition, we are making conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we are revising § 414.507(d) to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017 through March 31, 2017). In addition, as discussed in section III.A. of this final rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the conforming regulatory changes to the data reporting period would delay using updated private payor rate data and data reported by hospital outreach laboratories to set revised CLFS payment rates.

Due to the unforeseen changes in private payor rates, inclusion of hospital outreach laboratory data, and unpredictable nature of test volumes and their impact on calculating updated weighted medians private payor rates, we are uncertain as to whether the delay in data reporting would result in a measurable budgetary impact. In other words, in order to comprehend the impact of delayed reporting and subsequent implementation of updated CLFS rates, we would need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories, including the collection of private payor rate data from applicable hospital outreach laboratories, and calculate the updated weighted medians of private payor rates.

With regard to the conforming changes to our requirements for the phase-in of payment reductions, we note that this revision shifts the 15 percent limitation on payment reductions from CYs 2021 through 2023, to CYs 2022 through 2024. Therefore, we believe this conforming regulatory amendment to the phase-in of payment reductions in § 414.507(d) is budget neutral for scoring purposes.

2. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

We stated in section VII. of this final rule that:

- Section 424.67(b)(2) requires newly enrolling OTPs to pay an application fee at the time of enrollment under § 424.514.
- 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A. We project that all such changes will occur in CY 2021.
- 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B. We project that these changes will occur in CY 2022 and CY 2023 (roughly 5 changes per year).

These 310 OTPs would be required to pay an application fee because said change to a Form CMS–855A or Form CMS–855B enrollment would constitute a new/initial enrollment.

The application fees for each of the past 3 calendar years (CY) were or are $569 (CY 2018), $586, (CY 2019), and $595 (CY 2020). Consistent with § 424.514, the differing fee amounts are predicated on changes/increases in the Consumer Price Index (CPI) for all urban consumers (all items; United State city average, CPI–U) for the 12-month period ending on June 30 of the previous year. As stated in a notice published in the November 23, 2020 **Federal Register** titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2021'' (85 FR 74724), the fee amount for CY 2021 will be $599. This results in a total application fee cost for OTP changes to a Form CMS–855A enrollment of $179,700 ($599 × 300 OTPs).

Although we cannot predict changes to the CPI beyond CY 2021, the fee amounts between 2019 and 2021 increased by an average of $6 per year. We believe this is a reasonable barometer with which to estimate (strictly for projecting the total application fee costs for the 10 OTPs that we believe will switch to a Form CMS–855B enrollment) the fees for CY 2022 and CY 2023. Accordingly, we project a fee of $605 in CY 2022 and $611 in CY 2023. This results in a total application fee cost of $3,025 ($605 × 5 OTPs) in CY 2022 and $3,055 in CY 2023 ($611 × 5 OTPs). Over the next 3 years, therefore, the total application fee cost will be $185,780 ($179,700 + $3,025 + $3,055).

We received no comments on our application fee estimates.

3. Payment for Principal Care Management (PCM) Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

After reviewing the PFS, FQHC, and RHC historical spending, including the first quarter of calendar year 2020 spending for the new principal care management codes under the PFS, we estimate the addition of these codes (G2064 and G2065) to G0511 would have a negligible impact on Medicare spending.

4. Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Rebasing and Revising of the FQHC Market Basket

The CY 2021 FQHC market basket and multi-factor productivity adjustment is 0.1 percentage point higher under the 2017-based FQHC market basket (1.7 percent) compared to under the 2013-based market basket (1.6 percent). Therefore, the economic impact of finalizing the FQHC market basket rebasing and revising for CY 2021 is approximately $1M and we consider this impact to be negligible. We determined this amount by applying a factor of 0.001 to the FQHC baseline, which was approximately $1,100 million in calendar year 2019. Over the next 10 years the rebasing methodology results in, at most, a difference of 0.1 percent compared to the prior methodology but it is not always higher. The difference in the payment updates is projected to be higher in the next 2 years but then lower or the same beyond that. Therefore, this initial negligible cost decreases over time and overall estimated spending will likely be unaffected.

5. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention That Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

We are implementing section 2002 of the Support Act by adding regulatory language to the existing Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) regulations to explicitly include elements regarding screening for potential substance use disorders and a review of current opioid prescriptions. We expect the new regulatory elements to add minimal burden since review of medical and social history, risk factor

identification, education, counseling, and referrals are already fundamental parts of the IPPE and AWV. Standard documentation in the medical record that these services were furnished would not change based on these new requirements. We note that in section VIII.C.2.a. of this RIA, we discuss the increase in payment for E/M visits in general. Accordingly, the increase in payment for E/M visits applies to the IPPE and AWV and the impact to 2021 expenditures is included in section VIII.C.2.a. of this RIA.

6. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep electronic clinical quality measure (eCQM) specifications current and minimize complexity, we are aligning the eCQMs available for Medicaid EPs in 2021 with those available for MIPS eligible clinicians for the CY 2021 performance period. We anticipate that this alignment will reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change will not be significant, as many EPs are expected to report eCQMs to meet the quality performance category of MIPS, and therefore, should be prepared to report on those eCQMs for 2021. Not implementing this alignment could lead to increased burden because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program, if they opt to report on newly added eCQMs for MIPS. We expect that this policy will have only a minimal impact on states, by requiring minor adjustments to state systems for 2021 to maintain current eCQM lists and specifications. Based on a sampling of funding requests, each state typically spends, on average, approximately $670,000 per year to operate its Medicaid Promoting Interoperability Program attestation system for EPs. Only a small fraction of those costs is typically attributable to updating eCQM specifications. We estimate that the costs for updating eCQM specifications under the policy will be approximately $100,000 per state. State expenditures to make any systems changes that will be required as a result of the provision will most likely be eligible for 90 percent federal financial participation.

For 2021, we are requiring that Medicaid EPs report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy will generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). If no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she could report on any six eCQMs that are relevant. This policy will be a continuation of our policy for 2020 and we believe it will not create new burden for EPs or states.

7. Medicare Shared Savings Program

a. Modifications to the Shared Savings Program Quality Reporting Requirements and Quality Performance Standard for Performance Year 2021 and Subsequent Performance Years

In section III.G.1.c. of this final rule, we are finalizing a modified version of our original proposal to allow for a gradual phase-in of the increase in the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard and the retention of the CMS Web Interface collection type for performance year 2021. The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum losses under certain payment tracks, and avoid quality-related compliance actions.

Specifically, we are finalizing that an ACO would meet the quality performance standard if:

- For performance years 2021 and 2022, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores; and
- For performance year 2023 and subsequent performance years, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

We are also finalizing our proposal to exclude entities/providers eligible for facility-based scoring from the determination of the overall MIPS Quality performance category score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS), which includes quality and cost. Please refer to section III.G.1.c. of this final rule for a detailed discussion of the policies used to inform the impacts for the change to the quality performance standard.

Our analysis of quality performance data reported by ACOs for performance years starting during 2019 indicates that the methodological changes in ACO quality scoring will reduce the mean ACO quality score relative to recent historical performance years where ACO quality performance scores have averaged 90 percent or more. Despite an expectation for a decreasing score for most ACOs and potentially a slight increase in the fraction of ACOs failing to achieve the minimum threshold for qualifying for potential shared savings, the provision is estimated to marginally increase overall shared savings payments to ACOs initially because ACOs that meet the quality performance standard will be eligible to share in savings at the maximum sharing rate, rather than subject to variable sharing rates based on their quality performance score. Our best estimate is that shared savings payments to ACOs will increase by $60 million for the 2021 performance year because of these changes, representing an increase in shared savings payments of only about 3 percent of projected total gross measured savings for ACOs earning shared savings for that year. The corresponding estimated increase in payments to ACOs would slightly decrease to $40 million in 2022 because, beginning that year, ACOs would no longer have the option of utilizing the Web Interface reporting option, which is projected to be favorable for most ACOs. Then for 2023 when the quality performance standard will increase to the 40th percentile across all MIPS Quality performance category scores, assuming the distribution of ACO quality performance scores remains static from the 2019 base data, we project roughly 1-in-5 ACOs could fall below the 40th percentile and therefore shared savings payments to ACOs would decrease by approximately $100 million for that performance year. In total, these estimates sum to roughly a budget neutral outcome across the 3-year performance years covering 2021–2023.

These estimates (and in particular the estimated $100 million reduction in shared savings payments in 2023) could differ if the universe of MIPS Quality performance category scores improves relative to ACOs' quality performance scores, or alternatively if ACOs, particularly ACOs at risk of failing, respond to the methodology change by boosting their performance, especially by 2023 when the quality performance standard is to be increased from the 30th to the 40th percentile. Taking into account such possibilities indicates the

combined 3-year impact of the changes to the quality performance standard could differ from the budget neutral projection by up to +/−$200 million. Recognizing the uncertainty regarding these estimates, we will continue to monitor emerging performance to determine the impact of a measured increase to the quality performance standard and may revisit the policy in a future rulemaking in order to promote an attainable standard and degree of improvement based on initial performance under the new methodology.

b. Modifications to the Shared Savings Program Beneficiary Assignment Methodology and Repayment Mechanism Requirements

We do not anticipate a material aggregate impact for the other changes we are finalizing related to the Shared Savings Program, specifically the changes related to repayment mechanism requirements (section III.G.3. of this final rule) and the assignment methodology (section III.G.2. of this final rule); however, the assignment methodology provisions may have differing effects on a subset of participating ACOs, for example by changing the competing ACO to which a beneficiary ultimately is assigned, for a small subset of beneficiaries.

c. Finalization of Shared Savings Program Policies Established in the May 8th COVID–19 IFC

As discussed in section III.G.5 of this final rule, in the May 8th COVID–19 IFC we modified Shared Savings Program policies including to forgo the 2021 application cycle and allow eligible ACOs to elect a 1-year extension of their agreement period; allow eligible ACOs to temporarily freeze their position along the BASIC track's glide path for PY 2021; and adjust certain program calculations to remove Parts A and B expenditures for episodes of care for treatment of COVID–19; and expand the definition of primary care services used in determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19, beginning in January 2020 and for duration of the PHE for COVID–19. We are finalizing the Shared Savings Program's May 8th COVID–19 IFC provisions through this final rule with the following modifications. As discussed in section III.G.5.d. of this final rule, we are revising the regulation at § 425.611(b)(1)(ii) to align the timeframe for identifying discharges for acute care inpatient services for treatment of COVID–19 furnished by non-IPPS providers with the timeframe for the 20 percent adjustment to payments under the IPPS for individuals diagnosed with COVID–19 (which applies to discharges occurring during the PHE for COVID–19), for purposes of identifying episodes of care for treatment of COVID–19. As discussed in section III.G.5.e.(3) of this final rule, we are revising the regulation at § 425.400(c)(2) to specify that the additional primary care service codes will be used in conducting beneficiary assignment when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the PHE for COVID–19 defined in § 400.200. We are also adding a new provision at § 425.400(c)(2)(ii) to specify that we will apply the additional primary care service codes, specified in § 425.400(c)(2)(i) (as renumbered), to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) of the PHE for COVID–19 as defined in § 400.200.

In total, the changes to the Shared Savings Program described in the May 8th COVID–19 IFC were estimated to reduce program spending by $1.43 billion over the 2020 to 2025 period (ranging from a reduction of $790 million to $2.12 billion), with most of the reduction ($1.11 billion) attributable to performance year 2020. We do not anticipate a material aggregate impact from the aforementioned revisions to § 425.611(b)(1)(ii), specified in section III.G.5.d. of this final rule, and § 425.400(c)(2), specified in section III.G.5.e.(3) of this final rule.

8. Modifications to Medicare Shared Savings Program Quality Reporting Requirements for Performance Year 2020 and Finalization of Shared Savings Program Policies Established in the March 31st COVID–19 IFC

As discussed in section III.I.1. of this final rule, we are finalizing our proposal to waive the CAHPS for ACOs reporting requirement for performance year 2020 and will assign automatic full credit to all ACOs for the CAHPS for ACOs survey measures. Based on recent ACO performance on the CAHPS measures, we estimate moving to a 100 percent score for the CAHPS measures will increase the final quality score for the group of all non-new ACOs by roughly 2 percentage points. This would translate to an estimated increase in total shared savings payments to ACOs of approximately $20 million.

As discussed in section III.I.3. of this final rule, in the March 31st COVID–19 IFC, we modified the extreme and uncontrollable circumstances policy to eliminate the restriction that the policy applies only if the quality reporting period is not extended. We are finalizing this change without modification in this final rule. The total impact of extending the extreme and uncontrollable circumstances policy despite the extension of the quality reporting period for 2019 is estimated to be $20 million with a range of uncertainty in such estimate spanning $15 million to $25 million.

9. Removal of Selected National Coverage Determinations

We proposed to remove nine older NCDs that no longer contain clinically pertinent and current information or that involve items or services that are used infrequently by beneficiaries. We are removing six of the nine proposed. Generally, proactively removing obsolete or unnecessary NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. The NCDs fall into two impact categories. First, eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). Second, if the previous NCD barred coverage for an item or service under title XVIII, MACs would now be able to cover the item or service if the MAC determines that such action is appropriate under the statute. We believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries since we believe the future utilization for items and services within these policies will be limited, each affecting less than one percent of the Medicare FFS population.

For the three NCDs that are going from limited coverage to MAC discretion, claims data from 2019 show that less than one percent of the Medicare population are affected. Specifically, CMS provides limited coverage for specific conditions under NCD 20.5, Extracorporeal Immunoadsorption (ECI) using Protein A Columns, where CMS paid 1,918 Medicare FFS claims for 118 beneficiaries for a total expenditure of $3,757,178.36. Under NCD 100.9, Implantation of Gastroesophageal Reflux Device, CMS received no claims in

2019. CMS provides coverage for FDA approved labeled indications under NCD 110.19, Abarelix, and no claims were submitted in 2019 because the device is no longer marketed. If under MAC discretion, these items and services continue to be covered, we estimate there will be de minimis change to 2021 expenditures, compared to 2019. However, we note that MAC discretion may result in the MACs determining that in particular instances of these items and services, a noncoverage decision may be appropriate for the patient, which could result in a decrease in 2021 expenditures, compared to 2019. The three NCDs that we are not removing in this final rule, were also in this limited coverage category explained above. The current NCDs will continue to apply and we estimate there will be little significant difference in expenditures from 2019 to 2021. NCD 110.14, Apheresis (Therapeutic Pheresis), CMS paid 84,539 Medicare FFS claims for 10,641 beneficiaries for a total expenditure of $77,486,916.37. Under NCD 190.1, Histocompatability Testing, CMS paid 4,986 Medicare FFS claims for 2,525 beneficiaries for a total expenditure of $206,085.04. For NCD 190.3, Cytogenetic Studies, CMS paid 163,522 Medicare FFS claims for 145,212 beneficiaries for a total expenditure of $18,997,807.17.

For the three non-coverage NCDs we are removing, we would not expect to find historical claims data. We broadly noncover both Electrosleep Therapy (NCD 30.4) and Magnetic Resonance Imaging (NCD 220.2.1) for all indications. We noncover FDG PET (NCD 220.6.16) for three specific conditions. Because these NCDs provide for noncoverage, we do not have accurate claims data to estimate total impact. However, based on the diagnoses and services, we expect future claims to affect less than one percent of Medicare FFS beneficiaries. Furthermore, removing a national noncoverage NCD may reduce burden for stakeholders and CMS. It may also remove barriers to innovations and increase patient access to technologies that may now be beneficial for some uses.

10. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

This provision does not have any cost to stakeholders other than what is reflected in the Collection of Information section of this final rule, including cost to Medicare. We expect this to be a one-time burden estimate of 994,500 hours (165,750 * 6 hr) at a cost of $36,418,590 (994,500 hr * 36.62) to prescribers.

We received public comments about the impacts of this policy. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted the health care provider costs involved in implementing EPCS. One commenter recommended that CMS work with ONC to ensure that the cost of acquiring the electronic prescribing standard is part of the EHR certification criteria and to ensure that EHR developers cannot charge additional fees for building in this prescribing standard. Accordingly, the commenter requested that HHS take steps to minimize the cost of EPCS requirements to physician practices. Another commenter stated that their practice has delayed implementing EPCS due to the need to upgrade their EHR software, which has proven to be costly. The commenter stated that given the pandemic impact that amount is now unaffordable for their small primary care practice. Another commenter acknowledged that EPCS implementation costs can be high but that a prudent buyer of software support can find less expensive options.

Response: We share concerns about high health care provider costs associated with implementing EPCS, particularly during the PHE. An article in the Journal of the American Medical Association states that physicians in small private practices around the country have reported steep declines in revenues. Declining revenues have been so significant that some of practices have turned to GoFundMe.[152] However, neither ONC nor CMS have the authority to reduce EHR vendor charges for upgrades. We encourage those who provide software solutions to support EPCS make their products as accessible as possible and, as prescribers who do not implement the standard until 2022 will still be considered compliant, software providers will have more time to review their costs and for providers time to evaluate and chose among available options.

We have reflected these costs in our burden estimate in the Collection of Information section of this rule.

11. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

As discussed in section III.L. of this final rule, we are not finalizing the section 505(b)(2) drug product proposals or the proposed corresponding regulation text changes for 2021. Thus, there are no impacts for CY 2021.

12. Updates to Certified Electronic Health Record Technology Due to the 21st Century Cures Act

In section III.M. of this final rule, we are updating the definitions of CEHRT for the Promoting Interoperability Programs and for the MIPS Promoting Interoperability performance category. We are finalizing that health care providers may use technology certified to either the existing or updated 2015 Edition certification criteria, with the extended compliance date of December 31, 2022, as described in timelines finalized in the 21st Century Cures Act final rule (85 FR 25670) and the ONC interim final rule (85 FR 70064). After that time, when ONC only allows certification under the 2015 Edition Cures Update, health care providers must use only technology certified to the 2015 Edition Cures Update. Additionally, in section III.M.3.b, we are also implementing flexibility such that participants in the Hospital IQR Program may use either the 2015 Edition certification criteria, or the 2015 Edition Cures update for CEHRT beginning in the CY 2020 reporting period/FY 2022 payment determination.

With the final policies, eligible hospitals and clinicians, and eligible clinicians will be required to update their EHR technology to meet the CEHRT definition under the 2015 Edition Cures Update. It is important to note that the regulatory impacts of the ONC 21st Century Cures Act final rule account for the quantified and unquantified costs and benefits to hospitals and clinicians associated with acquiring technology certified to the 2015 Edition Cures Update (85 FR 25905 through 25938). Specifically, ONC based their analysis regarding the number of hospitals, CAHs, and eligible clinicians that would be impacted by their regulatory action on the number of hospitals, CAHs, and eligible professionals that have historically participated in the CMS EHR Incentive Programs (now called the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category) (85 FR 25908). Because we expect that the eligibility criteria proposed under this rule will be a subset of those who participated in the EHR Incentive Programs (for example, the MIPS program has eligibility criteria for low-volume that the EHR Incentive program did not have), this regulatory impact analysis assumes that the cost to program participants to acquire the

[152] *https://jamanetwork.com/journals/jama/fullarticle/2767633.*

upgraded technology has been accounted for under the ONC 21st Century Cures Act final rule. However, we acknowledged ambiguity in attributing impacts from the ONC 21st Century Cures Act final rule and this policy and requested comment that would help with identification of effects that are dependent on these new regulatory provisions. (We further noted that if the ambiguity is ultimately resolved such that all the costs are attributed to the ONC 21st Century Cures Act final rule, leaving no costs associated with this final rule's certified EHR provisions, then these provisions would also yield no benefits.) We did not receive comments on the additional effects of these regulatory provisions and therefore finalize that there is not additional burden or benefit beyond what is captured in the ONC 21st Century Cures act final rule.

13. Proposal To Establish New Code Categories

In section III.N. of this final rule, we maintain the existing 4 Level II HCPCS codes (J0572 through and including J0575), to identify the current array of buprenorphine/naloxone products available on the U.S. market. The number of codes available for health care providers and coders to identify and report on claims remains constant, and therefore no additional burden is placed on coders or health care providers.

14. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

a. Effects on Beneficiaries

In section III.O. of this final rule, we are finalizing certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to allow CMS to remove the once per life time benefit for some MDPP beneficiaries, increase the number of virtual sessions, allow MDPP suppliers to start new cohorts, and allow certain MDPP suppliers to deliver time-limited virtual MDPP sessions in the event of extreme and uncontrollable circumstances that would adversely affect access to MDPP services. These changes would apply during the PHE for COVID–19 and any future 1135 waiver event, in the emergency area during the emergency period, as defined under section 1135(g) of the Act, when the Secretary has authorized waivers under section 1135 for such emergency area and period and CMS has determined that the 1135 waiver event may disrupt in-person MDPP services.

Throughout the rulemaking for the MDPP expanded model, we sought to ensure that the set of MDPP services would be delivered in-person, in a classroom-based setting, within an established interval timeline. At the time, the priority was placed on establishing a structured service that, when delivered within the confines of the rule, would create the least risk of fraud and abuse, increase the likelihood of success, and maintain the integrity of the data collected for evaluation purposes. However, circumstances such as the PHE for COVID–19 have led CMS to make changes to the MDPP expanded model, and to implement an Emergency Policy for MDPP that allows for temporary flexibilities and that prioritizes availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by section 1135 waiver events.

In the March 31st COVID–19 IFC, we sought to ensure that the set of MDPP services that had already started when the PHE for COVID–19 began could continue given the guidance from CDC that Medicare age beneficiaries stay home. The priority was to allow for temporary flexibilities that prioritize availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by the PHE for COVID–19. Given the extended duration of the PHE for COVID–19, we are finalizing the regulations in the March 31st COVID–19 IFC, amend the MDPP expanded model to revise certain MDPP policies during the PHE for COVID–19 and any future 1135 waiver event where such 1135 waiver event may cause a disruption to in-person MDPP services. These temporary flexibilities allow beneficiaries to either continue to have access to set of MDPP services through virtual sessions, pause in-person set of MDPP services and resume with the most recent attendance session of record, or restart MDPP from the beginning in accordance with the March 31st COVID–19 IFC (85 FR 19230). Under the current MDPP regulations, as implemented in the IFC, and for future section 1135 events, should MDPP suppliers deliver set of MDPP services virtually and beneficiaries opt to continue with the set of MDPP services virtually during the 1135 waiver event, those beneficiaries are not eligible to restart the set of MDPP services at a later date.

b. Effects on the Market

At this point, we cannot make clear estimates of the true costs of the MDPP Emergency Policy costs given the current Medicare enrollment. For an example, as part of the COVID–19 flexibilities, we are using authority under section 1135 of the Act to waive the supplier enrollment application fee for any applications submitted on or after March 1, 2020 in response to COVID–19. This, along with CDC's promotion of the temporary application fee waiver to its DPRP registered organizations, have led to an increase in MDPP supplier enrollment applications and approved suppliers. Currently, more than 266 organizations nationally are enrolled as MDPP suppliers, representing 966 locations across the US and its territories.

For the current PHE for COVID–19, we anticipated in the March 31st COVID–19 IFC that of the 1,818 beneficiaries identified through our monitoring data and the CDC's Diabetes Prevention Recognition Program (DPRP) data, 1,358 beneficiaries may be impacted by allowing both the once-per-lifetime benefit and the minimum weight loss requirement to be waived for those beneficiaries in the first 12 months of MDPP. Of those, we assumed that roughly half of the beneficiaries will want to restart their set of MDPP services after the PHE for COVID–19 ends, with a $279,748 cost impact of our waiving the once-per-lifetime benefit as part of the COVID–19 flexibilities, assuming that the estimated cost of year 1 of MDPP is $412.

For this MDPP Emergency Policy, we are updating our assumptions, based on subsequent data from the CDC regarding DPRP organizations' plans for managing their existing cohorts during the PHE for COVID–19, which include either continuing with their cohorts virtually, pausing set of MDPP services and restarting them virtually, or restarting at a later date after the emergency event ends. Based on these data, we assume that 20 percent of MDPP suppliers and 20 percent of beneficiaries will want to restart the set of MDPP services at the first core session after the emergency event ends, taking advantage of the once-per-lifetime requirement removal. We assume that future emergencies will be more geographic-specific, resulting from a natural disaster versus the national-level PHE for COVID–19. For future emergencies, we assume that 2,500 beneficiaries will be enrolled in MDPP in the impacted geographic region. We note that this number is currently an overestimate, and over time, it will likely be an underestimate. We also note that these assumptions are incorrect in cases where a geographic region suffers widespread damage, including to electrical and/or telecommunications systems. This assumption is based on number of suppliers who have reported to the CDC that they are pausing their services during the current PHE for COVID–19.

For the current 1135 event, we are assuming 20 percent of 2,500 beneficiaries will want to take advantage of the waiver in 2020. In this scenario, we assume there would be no virtual or physical access to set of MDPP services for some time, and the supplier will need to either pause or restart classes altogether until such infrastructure systems are back in place. We also assume that beneficiaries who opt to continue with the set of MDPP services virtually are within the first 12 months of the MDPP core service period, and will not be eligible to take advantage of the waived once-per-lifetime limit; and beneficiaries who are in year 2 of the set of MDPP services, as demonstrated by the effective date of the first core session, are not eligible to restart MDPP at the beginning. The cost per impacted geographic area of the removal of the once-per-lifetime limit is estimated to be $209,000. This assumes that MDPP suppliers are paid an estimated $418 due to beneficiaries reaching the following performance milestones: Beneficiary attended 9 sessions, and reached the 5 percent weight loss during interval 2 of the core maintenance session, and attended the required core maintenance sessions.

TABLE 107: Cost of MDPP Emergency Policy per Geographic Area Impacted by the Emergency

Recommended Waivers	Cost impact
Adjust the limit to the # Virtual sessions	$ 0
Remove the once per lifetime requirement	$ 209
Remove the MDPP services time periods and intervals	$ 0
Average Y1 MDPP Payments (Y1) with no action	$ 0
Total cost of MDPP Emergency Policy per PHE	$ 209

Units of Measurement in thousands

Assumptions: Estimated MDPP payments in Year 1: $418, assuming that beneficiaries attended 9 sessions, and reached the 5 percent weight loss during interval 2 of the core maintenance session. For future emergencies we assume that 2,500 beneficiaries in any geographic area will be impacted by a public health emergency, or 500 beneficiaries per geographic area.

15. Changes Due to Updates to the Quality Payment Program

In section IV.A. of this final rule, we included our finalized policies for the Quality Payment Program. In this section of the final rule, we present the overall and incremental impacts to the number of expected QPs and associated APM Incentive Payments. In MIPS, we estimate the total MIPS eligible population and the payment impacts by practice size for the 2021 MIPS performance period based on various finalized policies to modify the MIPS final score and the performance threshold discussed in section IV.A.3.e.(3) of this final rule and additional performance threshold finalized in the CY 2020 PFS final rule (84 FR 63040). For this RIA, we updated performance period and eligibility data to reflect information submitted in the 2019 MIPS performance period.

a. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs, for the applicable performance period, will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payments for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs, but meet a lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment. For the 2021 QP Performance Period, as set forth in § 414.1430(a)(2), Partial QPs are eligible clinicians in Advanced APMs who have at least 50 percent, but less than 75 percent, of their payments for Part B covered professional services through an APM Entity, or furnish Part B covered professional services to at least 35 percent, but less than 50 percent, of their Medicare beneficiaries through an APM Entity. This MIPS payment adjustment may be positive, negative, or neutral. If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the Conversion Factor (CF) used to calculate payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while the CF used to calculate payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although the statute establishes overall payment rate and procedure parameters until 2026 and beyond, this impact

analysis covers only the fifth payment year (2023 payment year) of the Quality Payment Program.

Overall, we estimate that for the 2021 QP Performance Period between 196,000 and 252,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment in Payment Year 2023 based on 5 percent of their Part B paid amounts for covered professional services in the preceding year. These paid amounts for QPs are estimated to be between approximately $14,000 million and $18,500 million in total for the 2021 performance year. The analysis for this final rule used the 2019 third snapshot participation file. We based APM Incentive Payment Amounts on paid amounts with service dates of January 1, through September 30, 2019. We multiplied the calculated amounts by 1.5 to approximate payment amounts for the full calendar year. We estimate that the total lump sum APM Incentive Payments will be approximately $700–900 million for the 2023 Quality Payment Program payment year.

In section IV.F.10.b. of this final rule, we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2021 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2021 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. We note that the Next Generation ACO Model, previously scheduled to conclude December 2020, the Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), currently scheduled to conclude March 31, 2021, have been included in our analysis as we anticipate that these models will be Advanced APMs in 2021. The following APMs are expected to be Advanced APMs for the 2021 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), if extended;
- Comprehensive Primary Care Plus (CPC+) Model;
- Direct Contracting Model;
- Kidney Care Choices Model;
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare ACO Track 1+ Model;
- Next Generation ACO Model, if extended;
- Oncology Care Model (Two-Sided Risk Arrangements);
- Primary Care First (PCF) Model; and
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (*see* 81 FR 77444 through 77445 for information on the APM Participant Lists and QP determinations) for the Predictive QP determination file for 2019 to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2021 QP Performance Period. We examined the extent to which Advanced APM participants would meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

b. Impact for the 2022 MIPS Payment Year

In section IV.A.3.d.(2)(a) of this final rule, we finalized the proposal to double the total points available for the complex patient bonus to up to 10 points. We expect this finalized policy to result in the median bonus to increase by 3 points, thus increasing MIPS final scores at the median by 3 points. We do not know the effects of the PHE for COVID–19 and its effect on MIPS performance in 2020, so we did not recreate the analysis and payment distributions with the updated bonus for the 2020 MIPS performance period. We expect the higher MIPS final scores would result in smaller payment adjustments for two reasons. First, we expect reductions to the budget neutral pool due to the higher scores. Second, for clinicians above the performance threshold or additional performance threshold, an increased score would mean more clinicians sharing the budget neutral pool and additional $500 million for exceptional performance and potentially lowering the scaling factor that is applied to the MIPS payment adjustment and additional payment adjustment.

c. Impact of the PHE for COVID–19 on CY 2019 QPP Performance Period Submissions Data

The PHE for COVID–19 overlapped with the CY 2019 submissions period and led us to trigger our automatic extreme and uncontrollable circumstances policy for the entire U.S. for the 2019 MIPS performance period. This policy means that clinicians who did not submit any information to MIPS or for certain performance categories could have the performance category scores reweighted (instead of receiving a performance category score of 0). We also published in the March 31st COVID–19 IFC in which we updated our application-based extreme and uncontrollable circumstances policy to provide more flexibility for clinicians impacted by the PHE for COVID–19. Specifically, we extended the application deadline from December 31, 2019 to April 30, 2020, and also modified the policy at § 414.1380(c)(2)(i)(A)(6) to create an exception for the 2019 performance period/2021 MIPS payment year only, such that if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the PHE for the COVID–19 pandemic, but also submits data for the quality, Promoting Interoperability, or improvement activities performance categories, the performance categories for which data are submitted would still be reweighted and the data submission would not effectively void the application for reweighting (85 FR 19278).

As a result of these policies, we needed to assess whether it would be appropriate to use CY 2019 QPP submissions data to assess CY 2021 MIPS performance and whether adjustments would need to be made to the data because clinicians did not submit information. To do so, we examined the distribution of final scores for clinicians who submitted data to MIPS for the CY 2019 performance period, irrespective if they applied for the application-based extreme and uncontrollable circumstances policy we established in the March 31st COVID–19 IFC, and compared the levels of non-engagement in MIPS to the CY 2018 performance period. When we considered whether we should remove clinicians who received reweighting due to our triggering of the automatic extreme and uncontrollable circumstances policy due to the PHE for COVID–19, we found excluding clinicians under this policy led to an increase in the number of clinicians not engaged with MIPS compared to the CY

2021 PFS proposed rule RIA, which uses CY 2018 MIPS submissions data. These clinicians who did not submit data for the CY 2019 submissions period did not have shared characteristics that would warrant adjustment for their missing data. Therefore, we selected to only exclude clinicians who qualified for automatic E&U prior to COVID–19 to be consistent with the RIA methodology in previous years. When we considered clinicians impacted by updates to the application-based COVID–19 extreme and uncontrollable circumstances policy as finalized (85 FR 19278) on the CY 2019 submissions data, we found that including clinicians affected by the application-based extreme and uncontrollable circumstances policy in our CY 2021 PFS final rule RIA model did not lead to a meaningful difference in the distribution scores compared to when we used CY 2018 Quality Payment Program submissions data. Given these findings, we decided to use the CY 2019 submissions data and continued to exclude clinicians who were affected by the automatic extreme and uncontrollable circumstances prior to the PHE for COVID–19 as finalized (82 FR 53895 through 53900).

To avoid overestimating the positive payment adjustments for the 2021 MIPS performance period due to the increased number of MIPS eligible clinicians who are not engaged, we adjusted the paid amount of non-engaged clinicians for the CY 2021 MIPS performance period to equal their proportion of paid amount prior to the PHE for COVID–19. We conducted a sensitivity analysis to examine the expected payment adjustment for the CY 2021 MIPS performance period in the absence of an adjustment to the paid amount. The results from this sensitivity analysis are presented in section VIII.H.15.e.(3) of this final rule.

d. Estimated Number of Clinicians Eligible for MIPS Eligibility for the 2023 MIPS Payment Year

(1) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the 2021 MIPS performance period in this final rule, our scoring model used a combination of the first determination period from the 2020 MIPS performance period (from October 1, 2018 to September 30, 2019) and data from the end of calendar year 2019 (from October 1, 2019 to December 31, 2019). The first determination period from the 2020 MIPS performance period eligibility file was selected as it was the most recent eligibility file available. We included 1.6 million clinicians (*see* Table 108) who had PFS claims from October 1, 2018 to December 31, 2019. As discussed in section VIII.H.15.c. of this final rule, we excluded from our analysis individual clinicians who were affected by the automatic extreme and uncontrollable circumstances policy finalized for the 2018 MIPS performance period/2020 MIPS payment year in the CY 2019 PFS final rule (83 FR 59876) prior to the PHE for COVID–19 as we are unable to predict how these clinicians would perform in a year where there was no extreme and uncontrollable event. We also excluded from our analysis submissions from clinicians that are CPC+ practitioners due to data limitations and an inability to model their behavior within the APM Performance Pathway. Finally, we did not exclude submitters with one or more categories identified as being suppressed as a result of bad data for the CY 2019 performance period because we did not receive the list of CY 2019 submissions considered as bad data in time for this final rule.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group. Therefore, we excluded these clinicians when calculating the estimate of clinicians eligible for MIPS.

For the estimated MIPS eligible population for the 2023 MIPS payment year, we restricted our analysis to clinicians who are a physician (as defined in section 1861(r) of the Act), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); a physical therapist, occupational therapist, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional as finalized in the CY 2019 PFS final rule (83 FR 60076).

As noted previously, we excluded QPs from our scoring model since these clinicians are not MIPS eligible clinicians. To determine which clinicians in the initial population of 1.6 million should be excluded as QPs, we used Advanced APM payment and patient percentages from the APM Participant List for the first snapshot date for the 2020 QP performance period, supplemented by the most recent 2019 performance period APM participation data for those clinicians not on the 2020 first snapshot list. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2021 QP performance period. We assumed that all Partial QPs would elect to participate in MIPS and included them in our scoring model and eligibility counts. The projected number of QPs excluded from our model is 172,530. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2021 Medicare QP Performance Period; hence, our model may underestimate or overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we used the enrollment date from the 2019 Quality Payment Program performance period data.

(b) Assumptions Related To Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN) levels based on how data are submitted or at the APM Entity level if the clinician is part of an APM Entity in a MIPS APM (hereafter, a MIPS APM Entity) that elects to submit to MIPS. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment. Our method of modeling opt-in participation is described later in this section.

Table 108 presents the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.6 million clinicians in the analysis of the 2021 MIPS performance period after using 2019 MIPS performance period data and applying the finalized policies for the 2021 MIPS performance period.

To apply the low-volume threshold, we need to understand whether clinicians participate as a group, virtual group, APM entity, or as individuals. For the purposes of this regulatory impact analysis, we made assumptions as to which clinicians would elect group reporting, virtual group or APM Entity reporting. One extreme and unlikely assumption is that no practices elect

group reporting, virtual group reporting, or participate in an APM Entity that elects MIPS reporting and the low-volume threshold is applied at the individual level. Although we believe a scenario in which clinicians would only participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For this final rule model, we estimate approximately 228,000 clinicians [153] would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 108, we identify these clinicians as having ''required eligibility.''

For this RIA, we assume the following participation requirements for virtual groups and MIPS APM Entities that elect to participate in MIPS. We assume that TINs that registered as a virtual group for the CY 2019 MIPS performance period will continue to do so for the CY 2021 MIPS performance period. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, our model assumes ACO APM Entities would elect to submit data to MIPS through the APM Performance Pathway and that participants in non-ACO APM Entities would participate in MIPS as an individual or group rather than as an APM Entity. We included those who are in MIPS APM ACOs in the 2019 performance period as well as the additional clinicians in the first snapshot date of the 2020 QP performance period.

Finally, we assume that groups that submitted to MIPS as a group will continue to do so for the CY 2021 MIPS performance period. Using CY 2019 MIPS performance period data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data. Using these assumptions, we identified approximately 661,000 MIPS eligible clinicians who are eligible because they had the low-volume threshold applied to an identified group, APM entity, or virtual groups. In Table 108, we identify these clinicians who do not meet the low-volume threshold individually but are assumed to submit to MIPS as a group, virtual group or MIPS APM as having ''group eligibility.''

To model the opt-in policy finalized in the CY 2019 PFS final rule (83 FR 59735), we updated our methodology from the CY 2021 PFS proposed rule (85 FR 50384 through 50387) because actual opt-in participation data became available with the transition to the use of CY 2019 performance period data. We assumed clinicians who exceeded at least one but not all low-volume threshold criteria and who elected to opt-in to MIPS and submitted data for the CY 2019 MIPS performance period would also elect to opt-in to MIPS for the CY 2021 MIPS performance period.

These clinicians who met this opt-in participation assumption are identified in Table 108 as ''Opt-In eligibility''. In this final rule analysis, we estimate an additional 2,300 clinicians would be eligible through this ''opt-in'' policy for a total MIPS eligible clinician population of approximately 891,000. The leads to an associated $72 billion allowed PFS charges estimated to be included in the 2021 MIPS performance period.

[153] The count of 227,488 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (200,373 MIPS eligible clinicians), as well as those who did not participate (27,115 MIPS eligible clinicians).

TABLE 108: Description of MIPS Eligibility Status for CY 2023 MIPS Payment Year Using the CY 2021 PFS Final Rule Assumptions**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	CY 2021 PFS Final Rule estimates	
		Number of Clinicians	PFS allowed charges ($ in mil)*
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	200,372	$48,461
	Do not participate in MIPS	27,115	$6,345
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	660,909	$17,061
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	2,346	$51
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**890,742**	**$71,918**
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	381,771	$9,979
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	83,039	$460
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	269,905	$10,225
Total Number of Clinicians Not MIPS Eligible		734,715	$20,664
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,625,457	$92,582

* Estimated MIPS Eligible Clinician Population

** Table 108 does not include clinicians impacted by the automatic extreme and uncontrollable policy prior to PHE for COVID-19 (approximately 5,000 clinicians and $530 million in PFS allowed charges). It also does not include eligible clinicians in CPC+ APMs who otherwise would have been MIPS eligible.

*** Allowed charges estimated using 2018 and 2019 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

There are approximately 382,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate or they elect to opt-in. We describe this group as ''Potentially MIPS eligible''. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate the MIPS eligible clinician population could be as high as 1.3 million clinicians.

Finally, there are some clinicians who would not be MIPS eligible either because they and their group are below

the low-volume threshold on all three criteria (approximately 83,000) or because they are excluded for other reasons (approximately 270,000).

Since eligibility among many clinicians is contingent on submission to MIPS as a group, virtual group, APM participation in a MIPS APM Entity that elects to report to MIPS, or election to opt-in, we will not know the number of MIPS eligible clinicians until the submission period for the 2021 MIPS performance period is closed. For this impact analysis, we used the estimated population of 890,742 MIPS eligible clinicians described above.

e. Estimated Impacts on Payments to MIPS Eligible Clinicians for the 2023 MIPS Payment Year

(1) Summary of Approach

In sections IV.A.3.c., IV.A.3.d. and IV.A.3.e. of this final rule, we present several provisions which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VIII.H.15.e.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2023 MIPS payment year. We note that some of the MIPS policies in the CY 2020 PFS final rule were only defined for the 2020 MIPS performance period and 2022 MIPS payment year and did not continue to future years, such as the quality and cost performance category weights. Because we did not have category weights for the 2021 MIPS performance period, we could not calculate a final score for the 2021 MIPS performance period and 2023 MIPS payment year. Therefore, we could not create a baseline for the 2021 performance period that would allow us to fully distinguish between the impact of the previously finalized policies for the 2021 performance period and the finalized policies for the 2021 performance period. Our impact analysis looks at the total effect of the previously finalized and newly finalized MIPS policies on the MIPS final score and payment adjustment for the CY 2021 MIPS performance period/CY 2023 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is a value determined by their performance (as an individual, group, virtual group, or APM Entity) in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VIII.H.15.e.(2) of this final rule, we generally used the most recently available data from the Quality Payment Program which is data submitted for the 2019 MIPS performance period.

The estimated payment impacts presented in this final rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues that clinicians earn would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2021 Quality Payment Program for this final rule, we generally used 2019 MIPS performance period data. Our scoring model included the 890,742 estimated MIPS eligible clinicians as described in section VIII.H.15.b of this RIA.

To estimate the impact of MIPS policies on MIPS eligible clinicians, we generally used the 2019 MIPS performance period data, including data submitted for the quality, improvement activities, and Promoting Interoperability performance categories. We supplemented this information with CAHPS for MIPS and CAHPS for ACOs, the revised total per capita cost measure and Medicare Spending Per Beneficiary (MSPB) clinician measures that were finalized in the CY 2020 PFS final rule (84 FR 62969 through 62977), and other data sets.[154] We calculated a hypothetical final score for the 2021 MIPS performance period/2023 MIPS payment year for each MIPS eligible clinician using score estimates described in this section for quality, cost, Promoting Interoperability, and improvement activities performance categories.

[154] Data submitted to MIPS for the 2018 MIPS performance period data was used for the improvement score for the quality performance category. We also incorporated some additional data sources when available to represent more current data.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a similar methodology described in the CY 2020 PFS final rule (84 FR 63168 through 63169) with the following modifications that reflect the newly finalized policies for the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1)(e)(i) of this final rule, we finalized as proposed to replace the All-Cause Readmission measure with the Hospital Wide Readmission measure and add the hip-knee complications measure for those for whom it is applicable. We used testing data for these new administrative claims measures.

As discussed in section IV.A.3.d.(1)(b) of this final rule, we are not finalizing our intent to use a performance period benchmark as opposed to a historical benchmark. Therefore, we used the 2019 MIPS performance period benchmarks because the performance data for this analysis came primarily from the 2019 MIPS performance period. The one exception where we used the 2019 MIPS performance period benchmarks was when we identified measures subject to the topped out scoring cap that was finalized (82 FR 53721 through 53727) using the 2020 MIPS performance period benchmark file. As discussed in section IV.A.3.c.(1) of this final rule, we applied the finalized quality performance category weight of 40 percent for the 2021 MIPS performance period.

Finally, we finalized the APM Performance Pathway policies as described in section IV.A.3.b. of this final rule. The APM Performance Pathway is available for APM entities and as discussed in section IV.A.3.(b).(3).(a) we are finalizing an alternate measure set consisting of the Web Interface measures for the CY 2021 performance period. For our RIA model, we assumed clinicians in APM Entities would continue to use the Web Interface collection type, if available, over the APM Performance Pathway. Due to data limitations, our analysis only applied Web Interface and the APM Performance Pathway scoring policies to ACO APM Entities. For ACOs, quality performance under the finalized APM Performance Pathway was modeled using Web Interface data for 2019 from the 2019 performance period submissions data. For the multiple chronic condition unplanned admissions measure under the APM Performance Pathway, the 2019 Shared Savings Program and the 2018 Next Generation ACO Model public use files

were used.[155] To estimate the Hospital Wide Readmission measure as finalized in section IV.A.3.c.(1)(e)(i), we aggregated the score for APM Entities. Data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM Entities. Therefore, we assumed due to data limitations these non-ACO APM entities would not participate in the APP although they can participate in APP, either through the APP measures or Web Interface for the CY 2021 performance period. For the purposes of modeling, we assumed that their participating clinicians (or their groups) would participate in regular MIPS, and scored those clinicians using the available MIPS submissions of the clinician or its group. Therefore, because of data limitations our results may overestimate or underestimate the number of APM Entities that elect to participate in MIPS as an APM Entity and how they elect to participate.

(b) Methodology To Estimate the Cost Performance Category Score

In section IV.A.3.c.(2) of this final rule, we finalized as proposed a cost performance category weight of 20 percent for the 2021 MIPS performance period. We estimated the cost performance category score using the methodology described in the CY 2020 PFS final rule (84 FR 63169).

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As finalized in the CY 2019 PFS final rule (83 FR 59856), we determine the eligible clinician's MIPS cost and quality performance category score in facility-based measurement based on Hospital VBP Program Total Performance Score for eligible clinicians or groups who meet the eligibility criteria, which we designed to identify those who primarily furnish services within a hospital. We estimated the facility-based score using the scoring policies finalized in the CY2018 Quality Payment Program final rule (82 FR 53763) and the methodology described in the CY 2020 PFS final rule (84 FR 63169).

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

In section IV.3.c.(4)(c)(ii)(B), we are finalizing as proposed to add the HIE bi-directional exchange measure for the 2021 performance period and subsequent years as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. This provision provides clinicians the option of either reporting the new measure or the two existing measures. In section IV.3.c.(4)(c)(i) of this final rule, we finalized as proposed for the PDMP measure to remain optional and to double the bonus points from 5 to 10 points.

We used the CY 2019 MIPS Promoting Interoperability performance period data submissions data to estimate CY 2021 MIPS performance for the Promoting Interoperability performance category. Due to technical limitations, the data used do not capture the following policy changes between the CY 2019 and CY 2021 performance periods: (1) The doubling of the bonus points for clinicians who submitted the PDMP measure, (2) the removal of the Verify Opioid Treatment Agreement measure data, a measure that was finalized in the CY 2019 performance period (83 FR 59806) but removed in the CY 2020 performance period (84 FR 62994), and (3) the adoption of the finalized Health Information Exchange bi-directional exchange measure for the CY 2021 performance period. As a result, the estimated Promoting Interoperability performance category scores for the CY 2021 performance period may be a slight over- or under-estimate of performance in the Promoting Interoperability performance category.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2019 MIPS performance period data and APM participation identified in section VIII.H.15.b of this final rule. We continued to apply the methodology described in the CY 2020 PFS final rule (84 FR 63170) to assign an improvement activities performance category score. For the APM participants identified in section IV.A.3.b.(2) of this final rule, as there was no APM performance pathway score in the previous final rule, we assigned an improvement activity performance category score of 100 percent.

(f) Methodology To Estimate the Complex Patient Bonus

In section IV.A.3.d.(2)(a) of this final rule, we finalized as proposed to continue the complex patient bonus for the 2021 MIPS performance period. Consistent with the policy to define complex patients as those with high medical risk or with dual eligibility, our scoring model used the complex patient bonus information calculated for the 2019 performance period data.

(g) Methodology To Estimate the Final Score

As discussed in sections IV.A.3.c.(1)(b), IV.A.3.c.(2)(a), and summarized in section IV.A.3.d.(2)(b) of this final rule, our model assigned a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to section IV.A.3.d.(2)(b)(iii) of this final rule.

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in section IV.A.3.e.(2) of this final rule, we applied the finalized hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available.

We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and additional payment adjustment for exceptional performance (as finalized under § 414.1405), using the performance threshold of 60 points previously finalized in the CY 2020 PFS final rule (84 FR 63037) and the previously finalized additional performance threshold of 85 points (84 FR 63039 through 63040). In the alternatives considered discussed in section VIII.I.2. of this rule, we include the key statistics if the performance threshold was 50 as proposed in the CY 2021 PFS proposed rule (85 FR 50318). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the paid amount for covered

[155] The public use files for the 2019 Medicare Shared Savings Program and 2018 Next Generation ACO Model can be accessed at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-data* and *https://innovation.cms.gov/innovation-models/next-generation-aco-model.*

professional services furnished by the MIPS eligible clinician. As discussed in section VIII.H.15.c. of this final rule, we adjusted the paid amount of non-engaged clinicians to equal their proportion of paid amount prior to the PHE for COVID–19.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $458 million would be redistributed through budget neutrality and that $500 million would be distributed to MIPS eligible clinicians that meet or exceed the additional performance threshold. The mean final score is 79.80 and the median is 85.27.

The model further estimates that the maximum positive payment adjustments are 5.3 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In the alternatives considered discussed in section VIII.I.2. of this rule, we include the details of the model in which the performance threshold was set to 50, which had been proposed in the 2021 PFS proposed rule. In this alternate model, $388 million would be redistributed through budget neutrality and the maximum positive payment adjustments would be 4.9 percent.

Table 109 shows the impact of the payment adjustments by practice size and based on whether clinicians are expected to submit data to MIPS. We estimate that a smaller proportion of clinicians in small practices (1–15 clinicians) who participate in MIPS will receive a positive or neutral payment adjustment compared to larger sized practices. Table 109 also shows that 93.0 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. We want to highlight that we are using 2019 MIPS performance period submissions data to simulate a 2021 MIPS performance period final score, and it is likely that there will be changes that we cannot account for at this time, including services and payments disrupted by the PHE for COVID–19 or clinicians changing behavior because of the performance thresholds increased for the 2021 MIPS performance period to avoid a negative payment adjustment. In particular, we have not accounted for potential clinicians who might elect to apply for the extreme and uncontrollable circumstances policies for the CY 2021 performance period that we discuss in section IV.A.3.d.(2)(b)(iv)(B) of this final rule.

The combined impact of negative and positive adjustments and the additional positive adjustments for exceptional performance as a percent of paid amount among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because some MIPS eligible clinicians that do not submit data to MIPS receive a non-zero score for the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS. Among those who we estimate would not submit data to MIPS, 85 percent are in small practices (22,956 out of 27,115 clinicians who do not submit data). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs, which we describe in section H.15.e.(4)(b)(iv) of this final rule. We intend to continue working with stakeholders to improve engagement in MIPS among clinicians in small practices. It should also be noted that the estimated number of clinicians who do not submit data to MIPS may be an overestimate of non-engagement in MIPS for the CY 2021 MIPS performance period. This is because the PHE for COVID–19 may have resulted in fewer clinicians submitting data to MIPS or more clinicians may elect to apply for the extreme and uncontrollable circumstances policies due to the PHE for COVID–19 for 2021 MIPS performance period. Therefore, engagement levels in MIPS for the CY 2021 MIPS performance period may be differ from these reported estimates. We also note this participation data is generally based off participation for the 2019 performance period, which is associated with the 2021 MIPS payment year and had a performance threshold of 30 points, and that participation may change for the 2021 performance period when the performance threshold is 60 points.

TABLE 109: MIPS Estimated Payment Year 2023 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*[a]

Practice Size*	Number of MIPS eligible clinicians	Percent MIPS Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent MIPS Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent MIPS Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**
Among those submitting data* **					
1) 1-15	123,536	81.7%	46.9%	18.3%	1.0%
2) 16-24	40,688	87.5%	46.6%	12.5%	1.3%
3) 25-99	189,346	90.5%	50.6%	9.5%	1.5%
4) 100+	510,057	97.0%	55.6%	3.0%	1.7%
Overall	**863,627**	**93.0%**	**52.9%**	**7.0%**	**1.4%**
Among those not submitting data					
1) 1-15	22,956	0.0%	0.0%	100.0%	-8.6%
2) 16-24	1,225	0.0%	0.0%	100.0%	-8.7%
3) 25-99	2,212	0.0%	0.0%	100.0%	-8.7%
4) 100+	722	0.0%	0.0%	100.0%	-8.8%
Overall	**27,115**	**0.0%**	**0.0%**	**100.0%**	**-8.6%**

NOTE: Results of this model may change significantly if more clinicians apply for the application-based extreme and uncontrollable circumstances policy exception in CY 2021 because of the PHE for COVID-19.
*Practice size is the total number of TIN/NPIs in a TIN.
** 2019 data used to estimate 2021 performance period payment adjustments. Payments estimated using 2019 dollars trended to 2023. The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.
***Includes facility-based clinicians whose quality data is submitted through hospital programs.

As a sensitivity analysis of our COVID–19 adjustment on paid amount, we ran a model that did not adjust the paid amount of non-engaged clinicians to equal their proportion of paid amount prior to the PHE for COVID–19, our model estimates that $601 million would be redistributed through budget neutrality. The model further estimates that the maximum positive payment adjustments are 5.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance.

(4) Additional Impacts From Outside Payment Adjustments

(a) Burden Overall

In addition to the payment adjustments, we are finalizing several policies that have an impact on burden in the CY 2021 and CY 2022 MIPS performance periods. In section VII.B.5 of this final rule, we outline the costs of data collection that includes both policy updates and adjustments due to the use of updated data sources. For each finalized proposal included in this regulation which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 110. We also provide additional burden discussions that we are not able to quantify.

TABLE 110: Incremental Burden from Associated Finalized Policies

Burden Description and associated finalized proposals	Burden Hours	Burden Dollars
Total burden associated with continuing the policies and ICRs set forth in the CY 2020 PFS final rule into the 2021 and 2022 MIPS performance periods (as discussed in section VII.B.5.p)	1,478,504	$ 144,456,084
Burden change due to finalized policy to sunset the CMS Web Interface measures as a collection type/submission type for CY 2022*	-5,926	-$ 541,507
Burden change due to finalized policy to require QCDRs and qualified registries to conduct targeted data audits, if necessary	730	$ 67,496
Burden change due to new ICR for Nomination of MVPs	300	$ 45,467
Burden change due to finalized policy to add a survey-based measure on telehealth to the CAHPS for MIPS Survey	100	$ 2,565
Burden change due to finalized policy to allow APM Entities to submit an extreme and uncontrollable circumstances exception application	1.75	$ 162
Burden change due to finalized policy to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible	31	$ 4,698
Total change in burden due to policy	**-4,763**	**-$ 421,117**
Total burden set forth in the CY 2021 PFS final rule	**1,473,741**	**$ 144,034,968**

* The total change in burden due to this policy includes a decrease in burden due to elimination of the "Quality Data Submission: CMS Web Interface collection type" ICR beginning with the 2022 MIPS performance period and "Group Registration for CMS Web Interface" ICR beginning with the 2022 MIPS performance period as well as an increase in burden for the "Quality Data Submission: MIPS CQM and QCDR collection type" and "Quality Data Submission: eCQM collection type" ICRs beginning with the 2022 MIPS performance period for respondents who previously submitted via the CMS Web Interface submitting data via an alternate collection type. See section VII.B.5. of this final rule.

(b) Additional Impacts to Clinicians

(i) Web Interface

As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2022 performance period. We recognize that the sunset of the CMS Web Interface for groups and virtual groups may be burdensome to current groups and virtual groups submitting quality data on CMS Web Interface measures. Such groups and virtual groups will need to select a different collection type/submission type and redesign their systems to be able to interact with the new collection type/submission type. Given that the Medicare Part B claims collection type is limited to small practices, the alternatives for these groups and virtual groups will be either the MIPS CQM, QCDR or eCQM collection types. Given the size of the affected groups and virtual groups, we believe the majority are likely to already be using a QCDR, qualified registry, or EHR as part of their practice workflow. Of the 3,613 TINs comprised of 25 or more clinicians who submitted MIPS data via a collection type other than the CMS Web Interface, 57 percent reported via the MIPS CQM and QCDR collection type and 43 percent reported via the eCQM collection type. For groups converting from Web Interface, there will be some non-recurring costs associated with modifying clinical and MIPS data reporting workflows to utilize an alternate collection type. For any remaining groups and virtual groups there will also be registry fees paid to a QCDR or qualified registry or the financial expense of purchasing/licensing and deploying an EHR system. Because we are unable to assess either the existing workflows of each individual group and virtual group or the decisions each group and virtual group will make in response to this finalized proposal, we cannot quantify the resulting economic impact. While there may be an initial increase in burden for current groups and virtual groups utilizing the CMS Web Interface measures having to transition to the utilization of a different collection type/submission type, we recognize that we will also be reducing reporting requirements. Groups and virtual groups will no longer have to completely report on all pre-determined CMS Web Interface measures and will be able to select their own measures (at least 6) to report.

Groups and virtual groups account for less than 20 percent of organizations utilizing the CMS Web Interface measures while ACOs participating in the Medicare Shared Savings Program and Next Generation ACO Model account for more than 80 percent. With an 80 percent reduction and a continued decrease interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures, it is not fiscally viable, feasible, or sustainable for MIPS to continue to make available the CMS Web Interface measures as a collection type/submission type. There would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface. In assessing the utilization of the CMS Web Interface by groups and virtual groups, there has been a substantial decrease in participation each year since the inception of MIPS in the 2017 performance period. From 2017 to 2019, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the

CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS Web Interface as a collection type decreased by approximately 40 percent from 2017 to 2019. In our cost analysis, operating and maintaining the CMS Web Interface for significantly smaller number of groups and virtual groups would not be cost-effective. To operate and maintain the CMS Web Interface measures solely for groups and virtual groups, there would be an increase in cost and needed resources under MIPS associated with the items such as the establishment and maintenance of CMS Web Interface benchmarks, assignment and sampling, technical support, and education and outreach; thus, there would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface measures as a collection type/submission type.

(ii) Administrative Claims Measure

As discussed in section IV.A.3.c.(1)(d), we are finalizing as proposed to add two new administrative claims measures beginning in the 2021 MIPS performance period and for future performance periods. We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure that clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience. In summary, we are acknowledging that while there is no data submission requirements per § 414.1325(a)(2)(i) for administrative claim measures, there may be associated costs for clinicians and group practices to monitor new administrative claim measures; however, we are unable to quantify that impact.

(iii) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.3.c.(3)(b)(iii) of this final rule, we are finalizing the removal of one obsolete improvement activity, modification of two existing improvement activities, and adoption of the COVID–19 improvement activity added via IFC. We refer readers to Appendix 2 of this final rule for further details. We do not believe these finalized changes to the inventory will impact time or financial burden on stakeholders because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect these finalized changes to the inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate that the vast majority of clinicians performing improvement activities, to comply with existing MIPS policies, will continue to perform the same activities under the policies established in this final rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the 2020 MIPS performance period.

(c) Stakeholders Nominating Improvement Activities

In section IV.A.3.c.(3)(b)(i)(A)(bb) of this final rule, we are finalizing as proposed to make an exception to the established timeframe for nomination of improvement activities, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. While we expect additional nominations may be received as a result of this exception, we do not have any data with which to estimate what the additional number may be but we assume the additional costs associated with nominating new improvement activities are unchanged. Additionally, in section IV.A.3.c.(3)(b)(ii)(B) of this rule, we are finalizing as proposed beginning with the CY 2021 performance period and future years to consider agency-nominated improvement activities. We are unable to estimate the number of improvement activity nominations we will receive, but similar to the per respondent estimate we have provided in section VII.B.5.j. of this final rule, we assume it will require 3 hours at $55.75/hr for a GS–13 Step 5 to nominate an improvement activity for a total cost of $167.25 (3 hrs × $55.75/hr) per activity.

(iv) Impact on Small Practices

As described in section VIII.H.15.e.(3) of this final rule RIA, we found 85 percent of clinicians who did not submit data to MIPS were in small practices. However, the estimated number of MIPS eligible clinicians who do not submit data and receive a negative payment adjustment, including those in small practices, may be smaller in the CY 2021 performance period due to the PHE for COVID–19. For example, clinicians in small practices may avoid a negative payment adjustment due to non-engagement if they apply for the application-based extreme and uncontrollable circumstances policy exception for the CY 2021 performance period. Furthermore, CMS is committed to identifying flexibilities and options to help clinicians in small practices participate meaningfully and successfully in MIPS. Specifically, CMS excludes individual MIPS eligible clinicians or groups with less than or equal to $90,000 in allowed charges for covered professional services under the Medicare PFS, fewer than or equal to 200 Medicare Part B patients who are furnished covered professional services under the Medicare PFS, or fewer than or equal to 200 covered professional services under the Medicare PFS. We continue to give solo practitioners and practices with 10 or fewer clinicians the choice to form a virtual group to participate with other practices. For the quality performance category, we continue to: (1) Allow clinicians in small practices to continue submitting quality data for covered professional services at both the individual and group level through the Medicare Part B claims submission type; (2) award small practices 3 points for quality measures that don't meet data completeness requirements; and (3) award 6 bonus points to small practices, as long as one measure is submitted. For the Promoting Interoperability performance category, we continue to allow clinicians to apply to have this category reweighted to zero (if not qualified for automatic reweighting) for: (1) Small practices; (2) clinicians with insufficient internet connectivity; (3) clinicians with extreme and uncontrollable circumstances; (4) lack of control over availability of certified EHR technology (CEHRT); and (5) use of decertified EHR technology. For the improvement activities performance category, small practices and those in rural locations and in health professional shortage areas (or HPSAs) have reduced reporting requirements. For small practices or those located in a rural or HPSAs: (1) Medium-weighted activities are worth 20 points of the total category score; and (2) High-weighted activities are worth 40 points of the total category score. Finally, in terms of technical assistance, we launched the Small, Underserved,

and Rural Support initiative to provide free, customized technical assistance to clinicians in small practices. This 5-year program was funded by the Medicare Access and CHIP Reauthorization Act (MACRA). The Quality Payment Program technical assistance initiative in 2017 was part of our comprehensive education and outreach effort to help clinicians successfully participate in the Quality Payment Program. Our technical assistance achieved notable success during the first 2 years of the program, including receiving customer satisfaction ratings of 99.8 percent in 2017 and 98.7 percent in 2018. We also recognize that our technical assistance initiative led to a 95 percent participate rate in 2017.

(d) Impact on Third Party Intermediaries

In section IV.A.3.g. of this rule, we finalized as proposed multiple changes to the third party intermediary regulations at § 414.1400. Specifically, we are: (1) Amending current requirements for approval of third party intermediaries to take into account past performance and provision of inaccurate information regarding MIPS program requirements to eligible clinicians; (2) requiring attendance by all third party intermediaries for training and support sessions; (3) requiring that QCDRs and qualified registries must conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits; (4) incrementally increasing requirements for QCDR measure testing and clarify what is meant by full testing; and (5) requiring third party intermediaries to submit a CAP to address identified deficiencies and data issues as well as actions to prevent recurrence.

With regard to the amendments to current requirements for approval of third party intermediaries, we do not anticipate this to require any additional effort for affected entities as the revision is to allow CMS to utilize already available information to make approval decisions.

The finalized requirement for attendance at training and support sessions and the associated burdens on third parties closely aligns to expectations previously established in the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77374) and (81 FR 77384 through 77386). With regard to survey vendors, we previously finalized the CMS-approved survey vendor approval criteria in § 414.1400(e) as discussed in the CY 2018 PFS final rule (83 FR 59907 through 59908). Among the approval criteria, § 414.1400(e)(3) established the requirement that the entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors. Therefore, we assume no additional impact for survey vendors as a result of this finalized proposal. We do not have data on the number of health IT vendors that missed training and support sessions, but the most recent data cites 684 health IT developers through program year 2016 of the Medicare EHR Incentive Program.[156] In CY 2019, 16 total training and support sessions were missed by 14 QCDRs and 33 total sessions were missed by 27 qualified registries. Based on historical frequency and duration, we expect future training and support sessions to continue occurring monthly for approximately 2 hours each. For QCDRs and qualified registries, we estimate an impact of 98 hours [(16 sessions by QCDRs + 33 sessions by qualified registries) × 2 hours]. We lack insight into the exact occupation of session attendees, but for estimating purposes we assume a Physician labor rate of $212.78/hr and estimate a total burden of $20,852 ($212.78/hr × 98 hours).

We do not anticipate a significant impact to QCDRs and qualified registries resulting from the finalized proposal to require QCDRs and qualified registries to conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits. First, we are not revising our burden estimates because the finalized data validation requirements are similar to existing expectations which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999). Second, we believe that the finalized requirements for conduct of the data validation audits are aligned with methods and procedures which stakeholders currently utilize.

With regard to the proposal to require QCDRs and qualified registries to conduct targeted audits if one or more data errors are identified during data validation audits, we sought comment on the expected frequency of targeted audits and the anticipated scope of effort. We did not receive comments related to the expected frequency of targeted audits and the anticipated scope of the effort. However, we are including burden estimates associated with this finalized requirement in section VII.B.5.c.(2) and (3) of the Collection of Information for this rule. Due to the unknown scope of patient records that may need to be audited, we estimate a range of effort to complete a targeted data audit from a minimum of 5 hours to a maximum of 10 hours at a cost ranging from $462.30 ($92.46/hr × 5 hrs) to $924.60 ($92.46/hr × 10 hrs) per targeted audit. In the 2019 MIPS performance period, 37 of the 84 qualified registries (44%) and 23 of the 77 QCDRs (30%) that submitted 2019 MIPS quality data were required to complete a targeted audit. Based on the results of the 2020 self-nomination period, 58 QCDRs and 127 qualified registries have been approved for the 2021 MIPS performance period; assuming the same percentages, we estimate a total of 73 QCDRs and qualified registries (58 × 30% + 127 × 44%) will be required to complete targeted audits. Per these assumptions, we estimate the total impact associated with completing targeted audits will range from 365 hours (73 audits × 5 hrs/audit) at a cost of $33,748 (73 audits × $462.30/audit) to 730 hours (73 audits × 10 hrs/audit) at a cost of $67,496 (73 audits × $924.60/audit).

Because the finalized proposal to incrementally increase requirements for QCDR measure testing is not changing the requirements for fully testing measures, but is instead implementing an incremental approach to achieve previously finalized requirements, we do not anticipate any additional impact as a result of the finalized policy.

As discussed in section VII.B.5.c.(3) of this rule, we estimate the total burden impact associated with the provision to require CAPs to be 30 hours (10 respondents × 3 hr/respondent) at a cost of $2,774 for all respondents (10 respondents × $277.38/respondent).

f. Assumptions & Limitations

We note several limitations to our estimates of clinicians' MIPS eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2023 MIPS payment year. Due to the PHE for COVID–19, we are aware that there may be changes in health care delivery and billing patterns that will impact results for the 2023 MIPS payment year that we were not able to model with our historic data sources. The scoring model results presented in this final rule assume that CY 2019 Quality Payment Program data submissions and performance are representative of CY 2021 Quality Payment Program data submissions and performance. The estimated performance for CY 2021 MIPS

[156] *https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php.*

performance period using CY 2019 Quality Payment Program data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2019 MIPS performance period/2021 MIPS payment year was significantly lower (30 out of 100 points) than the performance threshold for the 2021 MIPS performance period/2023 MIPS payment year (60 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment. Finally, with the PHE for COVID–19 continuing in the 2021 MIPS performance period, we are uncertain of how many clinicians will apply for extreme and uncontrollable circumstances policy and not be required to submit data to MIPS.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in in the CY 2019 Quality Payment Program and submitted data would continue to elect to opt-in in the CY 2020 performance period. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the finalized policies.

There are additional limitations to our estimates: (1) To the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 109; and (2) our cost data does not overlap with CY 2019 so we may not be capturing performance for all clinicians. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify.

I. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented the estimated impact on total allowed charges by specialty.

1. Alternatives Considered for the MDPP Expanded Model Emergency Policy

For the MDPP Expanded Model Emergency Policy, no alternatives were considered. If we do not take action it will have an extremely negative impact to MDPP supplier and beneficiaries; which would threaten the success of the entire expanded model; as beneficiaries would become ineligible and not be able to finish the program, MDPP suppliers would not be paid for services rendered, and no new cohorts of set of MDPP services could be started, effectively ending the expanded model test.

2. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran a separate model with a performance threshold of 50 which was previously proposed in the CY 2021 PFS proposed rule (85 FR 50318) as an alternative to the finalized performance threshold of 60. The model with a performance threshold of 50 has the same mean and median final score as our model of finalized policies since the performance threshold does not change the final score. We estimate that $388 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 4.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 4.5 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

In addition, we view the cost performance category weight as a critical factor affecting final scores. We ran two separate models with cost performance category weights of 15 and 30, with corresponding quality performance category weights of 45 and 30, respectively (as an alternative to the finalized cost performance category weight of 20 and quality performance category weight of 40) to estimate the impact of keeping the weights consistent with the CY 2020 PFS final rule and a more aggressive increase in the cost performance category weight. The model with a cost performance category weight of 15 has a mean score of 80.21 and a median score of 86.07. The model with a cost performance category weight of 30 has a mean score of 78.38 and a median score 83.18. We refer readers to section IV.A.3.c.(2)(a) for additional discussion on the selection of the cost performance category weight.

Finally, we report the findings if Web Interface were removed as a collection type in the CY 2021 performance period. The model with the removal of Web Interface as a collection type has a final score mean of 78.36 and median of 83.05. We estimate that $459 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 6.6 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 7.2 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

3. Alternatives Considered for Changes Related to Scopes of Practice

With regard to the proposal concerning supervision of diagnostic tests by certain NPPs, an alternative would be to maintain the status quo. That is, we could maintain the basic rule under § 410.32(b)(1) that allows only physicians as defined under Medicare law to supervise the performance of diagnostic tests. In that case, the pool of practitioners who could supervise diagnostic tests would remain at current levels and certain NPPs would be limited under Medicare from practicing to the full extent allowed by their state license and scope of practice. However, this alternative would fail to address the mandates established in E.O. 13890.

With regard to the provision to allow a PTA/OTA to furnish maintenance therapy services, an alternative would be maintaining the status quo to require the PT/OT to personally furnish all maintenance therapy services. However, this alternative would not address the mandates established in E.O. 13890. It would also be inconsistent with our policy in SNF and home health settings when payment for therapy is made under Part A, maintenance therapy can be furnished by a PT/OT or delegated to be performed by a PTA/OTA.

4. Alternatives Considered for Refinements to Values for Certain Services To Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability During the PHE for COVID–19

As we noted in section II.F. of this final rule, we sought comment on how we might refine the utilization assumptions for HCPCS add on code G2211. In the proposed rule, we assumed that HCPCS add-on code G2211 would be reported with all office/outpatient visits for the specialties listed in the following public use file at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-EM-Add-on-Code.zip.*

As we discussed in section II.F. of this final rule, we considered alternative assumptions regarding utilization for HCPCS add-on code G2211. Several commenters suggested that CMS reduce its utilization assumptions to between 10 percent and 25 percent of reported office/outpatient E/M visits and could range as high as 25 percent of reported office/outpatient E/M visits. These commenters cited that it would take time for medical societies to educate their members about appropriate use, ongoing implementation of the office/outpatient E/M visit codes, electronic health records integration, and the persistence of the COVID–19 pandemic in many parts of the country. Thus, one alternative was to assume that HCPCS add-on code G2211 would be reported for 25 percent of office/outpatient E/M visits listed in the public use file. As we noted in section II.F. of this final rule, while we generally agree with commenters that practitioners will not report HCPCS add-on code G2211 with every visit, we disagree that it will be as low as 25 percent of all reported visits.

We also considered an alternative where these specialties would report HCPCS add-on code G2211 with their office/outpatient E/M visits 90 percent of the time. As we noted in section II.F. of this final rule, because we are not implementing any additional policies that restrict the billing of this code, we are assuming that utilization will be 90 percent of office/outpatient E/M visits for these specialties.

J. Impact on Beneficiaries

We do not believe these provisions will have a negative impact on beneficiaries given overall PFS budget neutrality.

1. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

This change would have a positive impact on affected MDPP beneficiaries, as it would allow them to maintain eligibility for the program, and request virtual sessions if needed for successful completion of attendance and weight loss milestones. It would also allow them to start set of MDPP services virtually, allowing remote digital technology to capture body weight measurement or self-reported weight measurements from a participant's personal home digital scale. Finally, if continuing with set of MDPP services is not an option for beneficiaries during the PHE for COVID–19, the Emergency Policy allows beneficiaries to restart their set of MDPP services, maximizing beneficiary options and access to MDPP both during the PHE for COVID–19 and after it ends.

2. Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment.

K. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $885.92 (8.0 hours × $110.74). Therefore, we estimated that the total cost of reviewing this regulation is $35,637,904 ($885.92 × 40,227 reviewers on this year's proposed rule).

L. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 111 and 112 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2020 to CY 2021 based on the FY 2021 President's Budget baseline.

TABLE 111: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2021 Annualized Monetized Transfers	Estimated increase in expenditures of $0.0 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 112: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2021 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.0 billion
From Whom to Whom?	Beneficiaries to Federal Government.

M. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

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

PART 400—INTRODUCTION; DEFINITIONS

■ 1. The authority citation for part 400 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 44 U.S.C. Chapter 35.

■ 2. Section 400.200 is amended by revising the definition of ''Public Health Emergency'' to read as follows:

§ 400.200 General definitions.

* * * * *

Public Health Emergency (PHE) means the Public Health Emergency determined to exist nationwide as of January 27, 2020, by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 4. Section 410.15 is amended in paragraph (a)—

■ a. By adding a definition for ''A review of any current opioid prescriptions'' in alphabetical order;

■ b. In the definition of ''First annual wellness visit providing personalized prevention plan services'' by revising paragraph (xi) and adding paragraphs (xii) and (xiii);

■ c. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'' by revising paragraph (ix) and adding paragraphs (x) and (xi).

The additions and revisions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

* * * * *

First annual wellness visit providing personalized prevention plan services * * *

(xi) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(xii) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xiii) Any other element determined appropriate through the national coverage determination process.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services * * *

(ix) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(x) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xi) Any other element determined appropriate through the national coverage determination process.

* * * * *

■ 5. Section 410.16 is amended in paragraph (a)—

■ a. By adding the definition for ''A review of any current opioid prescriptions'' in alphabetical order;

■ b. In the definition of ''Initial preventive physical examination'' by revising paragraphs (6) and (7) and adding paragraphs (8) and (9).

The additions and revisions read as follows:

§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.

(a) * * *

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

* * * * *

Initial preventive physical examination * * *

(6) A review of any current opioid prescriptions as defined in this section.

(7) Screening for potential substance use disorders to include a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(8) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(9) Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

* * * * *

■ 6. Section 410.32 is amended by—

■ a. Revising paragraphs (b)(1) and (b)(2)(iii)(B);

■ b. Adding paragraph (b)(2)(ix); and

■ c. Revising paragraph (b)(3)(ii).

The revisions and addition read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) * * *

(iii) * * *

(B) Furnished under the general supervision of a physician or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.

* * * * *

(ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.

(3) * * *

(ii) *Direct supervision* in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or, December 31, 2021, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

■ 7. Section 410.67 is amended—

■ a. In paragraph (b), by revising paragraph (7) and adding paragraph (8) in the definition of ''Opioid use disorder treatment service'';

■ b. By revising paragraph (d)(2)(i)(A); and

■ c. By adding paragraph (d)(4)(i)(E).

The additions and revision read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service * * *

(7) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency, as defined in § 400.200 of this chapter, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

(8) Opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(A) *Implantable and injectable medications.* For implantable and injectable medications, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the wholesale acquisition cost (WAC), if WAC is used.

* * * * *

(4) * * *

(i) * * *

(E) Take-home supply of opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication, an adjustment will be made when these medications are dispensed. This adjustment will be limited to once every 30 days, except when a further take home supply of these medications is medically reasonable and necessary. The opioid treatment program must document in the medical record the reason(s) for the exception. The amount of the drug component of the

adjustment will be determined using the methodology in paragraph (d)(2)(i) of this section. The amount of the non-drug component of the adjustment will be determined based on the CY 2020 Medicare payment rate for CPT code 96161.

* * * * *

■ 8. Section 410.78 is amended by revising paragraph (a)(3) and (f) to read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

* * * * *

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. During the Public Health Emergency, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list during the Public Health Emergency, taking into consideration infection control, patient safety, and other public health concerns resulting from the emergency. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services on the CMS website.

■ 9. Section 410.79 is amended by revising paragraphs (c)(3)(i) and (ii) and (e) to read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(c) * * *

(3) * * *

(i) Except as set forth in paragraph (c)(3)(ii) of this section—

(A) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(B) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(1)(ii) of this section, the MDPP services period ends upon completion of that maintenance session interval, unless the MDPP beneficiary qualifies for a subsequent ongoing maintenance session interval, in accordance with paragraph (c)(1)(iii) of this section, in which case the MDPP service period ends upon completion of the last ongoing maintenance session interval for which the beneficiary qualified.

(ii) In the case of an applicable 1135 waiver event as defined in paragraph (e) of this section, the MDPP services period may be suspended and resumed or restarted in accordance with paragraph (e) of this section.

* * * * *

(e) *MDPP expanded model emergency policy.* (1) Notwithstanding paragraphs (a) through (d) of this section, the policies described in this paragraph (e) apply during the Public Health Emergency (PHE) as defined in § 400.200 of this chapter and during any future 1135 waiver event that CMS determines may disrupts in-person MDPP services (an ''applicable 1135 waiver event''). For purposes of this paragraph (e), ''1135 waiver event'' means an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized one or more waivers under section 1135 of the Act.

(2)(i) CMS determines that an 1135 waiver event may disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include, but are not limited to, the avoidance of transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries and MDPP coaches, as defined in § 424.205(a) of this chapter, during an 1135 waiver event.

(ii) If CMS determines that an 1135 waiver event may disrupt in-person MDPP services, CMS will communicate such determination for purposes of the policies described in this paragraph (e), to all affected MDPP suppliers.

(3) The following changes apply under this paragraph (e), when CMS has determined that an 1135 waiver event may disrupt in-person MDPP services:

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A) and (c)(1)(iii)(A) of this section do not apply.

(ii) MDPP suppliers may start new cohorts during the PHE as defined in § 400.200 of this chapter or an applicable 1135 waiver event only if a baseline weight measurement can be obtained as described in paragraph (e)(3)(iii) of this section.

(iii) MDPP suppliers can obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss based performance achievement goals in the following manner:

(A) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations;

(B) Via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, a date-stamped photo or video recording of the beneficiary's weight with the beneficiary visible on the scale, or a recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session.

(iv) The virtual session limits described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. If the beneficiary began the MDPP services period virtually, or changed from in-person to virtual services during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may continue to receive the MDPP set of services virtually even after the PHE or 1135 waiver event has concluded, until the end of the beneficiary's MDPP services period, so long as the provision of virtual services complies with all of the following requirements:

(A) The curriculum furnished during the virtual session addresses the same CDC-approved DPP curriculum topic as the regularly scheduled session.

(B) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session on the same day as a regularly scheduled session.

(C) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session per week.

(D) Virtual sessions are furnished in a manner consistent with the DPRP standards for virtual sessions.

(E) The MDPP supplier offers virtual sessions only upon an individual MDPP beneficiary's request or agreement to receive services virtually.

(F) The MDPP supplier offers to an MDPP beneficiary:

(*1*) No more than 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(*2*) No more than 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period; and

(*3*) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24.

(v) MDPP suppliers may suspend the in-person delivery of the set of MDPP services, when necessary due to the applicable 1135 waiver event, and subsequently resume in-person services either upon the end date of the 1135 waiver event emergency period or an effective date specified by CMS. Upon resumption of the set of MDPP services on an in-person basis, the following paragraphs apply:

(A) Beneficiaries who were receiving MDPP services as of March 31, 2020 whose in-person sessions are suspended due to the PHE as defined in § 400.200 of this chapter may elect to restart the set of MDPP services at the beginning or resume with the most recent attendance session of record.

(B) Beneficiaries who begin the set of MDPP services on or after January 1, 2021 who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may elect to restart the set of MDPP services at the beginning or may resume with the most recent attendance session of record.

(C) Beneficiaries who began the set of MDPP services on or after January 1, 2021 who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record.

(D) Beneficiaries whose in-person sessions are suspended due to the applicable 1135 waiver event who elect to continue with MDPP services virtually, as described in paragraph (e)(2)(i) of this section, are not eligible to restart the set of MDPP services at a later date, but may elect to suspend the virtual set of MDPP services and resume the set of in-person MDPP services with the most recent attendance session of record.

(E) Beneficiaries may make an election as described in paragraph (e)(3)(v)(A), (B), (C), or (D) of this section, as applicable, only one time per applicable1135 waiver event.

(F) Beneficiary eligibility, as described in paragraph (c)(1)(i) of this section, will not be impacted by any changes to the beneficiary's body mass index (BMI) or reduction in hemoglobin A1c, fasting plasma glucose, or 2-hour plasma glucose test values achieved during the set of MDPP services or any intervening time in which a beneficiary has suspended the set of MDPP services. MDPP suppliers will utilize the following weight measurements as the baseline weight for purposes of determining all weight-loss achievements:

(*1*) For an MDPP beneficiary who began receiving the set of MDPP services before March 31, 2020, has suspended services during an applicable 1135 waiver event, and then elects to restart the set of MDPP services at the first core session, the MDPP supplier must record a new baseline weight on the date of first core session that restarts the set of MDPP services.

(*2*) For an MDPP beneficiary who began receiving the set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, and then resumes the set of MDPP services either at the most recent attendance session of record or restarts the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

(vi) The minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) of this section are waived only for MDPP beneficiaries who were receiving the MDPP set of services prior to January 1, 2021.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 10. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 11. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2022 through March 31, 2022.

* * * * *

■ 12. Section 414.504 is amended by revising paragraph (a)(1) to read as follows:

§ 414.504 Data reporting requirements.

(a) * * *

(1) For CDLTs that are not ADLTs, initially January 1, 2017 and every 3 years beginning January 1, 2022.

* * * * *

■ 13. Section 414.507 is amended by revising paragraphs (d) introductory text and (d)(4) and adding paragraph (d)(7) to read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2024, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(4) 2021—0.0 percent of the payment rate established in 2020.

* * * * *

(7) 2024—15 percent of the payment rate established in 2023.

* * * * *

■ 14. Section 414.1305 is amended—
■ a. By revising the definition of ''Attestation'';
■ b. In the definition of ''Certified Electronic Health Record Technology (CEHRT)'' by revising paragraphs (1)(ii)(D) and (2)(ii) introductory text;
■ c. By revising the definition of ''Collection type'';
■ d. By removing the definition of ''Full TIN APM'';
■ e. By revising the definitions of ''Low-volume threshold'', ''Meaningful EHR user for MIPS'', and ''MIPS APM'';
■ f. By adding definition for ''Physician Compare'' in alphabetical order; and
■ g. By revising the definitions of ''Primary care services'', ''Submission type'', and ''Submitter type''.

The revisions and addition read as follows:

§ 414.1305 Definitions.

* * * * *

Attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician or group may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

(1) * * *

(ii) * * *

(D) The certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

* * * * *

(2) * * *

(ii) Necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category including the following:

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the 2019 through 2023 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures.

* * * * *

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to $90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) For the 2021 and 2022 MIPS payment years, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

(5) Beginning with the 2023 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

Meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, and reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, supports information exchange and the prevention of health information blocking, and engages in activities related to supporting providers with the performance of CEHRT.

* * * * *

MIPS APM means:

(1) For the 2019 through 2022 MIPS payment years, an APM that meets the criteria specified under § 414.1370(b).

(2) Beginning with the 2023 MIPS payment year, an APM that meets the criteria as set forth in § 414.1367(b).

* * * * *

Physician Compare means the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Primary care services for purposes of CMS Web Interface and CAHPS for MIPS survey beneficiary assignment means the set of services identified by the following:

(1) CPT codes:

(i) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

(ii) Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital evaluation and management services (e-visit)); 99441,

99442, and 99443 (codes for telephone evaluation and management services); and 96160 and 96161 (codes for administration of health risk assessment).

(2) HCPCS codes:

(i) G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

(ii) Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

* * * * *

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to:

(1) Direct;

(2) Log in and upload;

(3) Log in and attest;

(4) Medicare Part B claims; and

(5) For the 2019 through 2023 MIPS payment years, the CMS Web Interface.

Submitter type means the MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, or APM Entity, as applicable, that submits data on measures and activities under MIPS.

* * * * *

■ 15. Section 414.1310 is amended by revising paragraphs (b)(1)(iii) and (e)(1) to read as follows:

§ 414.1310 Applicability.

* * * * *

(b) * * *

(1) * * *

(iii) Does not exceed the low volume threshold.

(A) Beginning with the 2021 MIPS payment year, if an individual eligible clinician or group exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician or group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under § 414.1315 constitutes an election under this paragraph (b)(1)(iii)(A) and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year.

(B) For the 2021 and 2022 MIPS payment years, if an APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year.

* * * * *

(e) * * *

(1) Except as provided under §§ 414.1317(b) and 414.1370(f)(2), each MIPS eligible clinician in the group will receive a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) based on the group's combined performance assessment.

* * * * *

■ 16. Section 414.1317 is added to read as follows:

§ 414.1317 APM Entity groups.

(a) *APM entity group determination.* The APM Entity group will be determined according to the requirements set forth in § 414.1425(b)(1).

(1) In addition to the dates set forth in § 414.1425(b)(1), for purposes of MIPS, the APM Entity group includes an eligible clinician who is on a Participation List on December 31 of the MIPS performance period.

(2) For purposes of MIPS scoring, the APM Entity group will be comprised only of those eligible clinicians within the APM Entity group who are determined to be MIPS eligible at the individual or group level.

(3) For purposes of calculating the APM Entity group score, MIPS scores submitted by virtual groups will not be included.

(b) *APM Entity group scoring.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) *Determination of performance category score for each MIPS eligible clinician in an APM Entity.* For APM Entities, where a performance category is not reported by the APM Entity, CMS uses one score for each MIPS eligible clinician in an APM Entity group to derive a single average APM Entity score for the performance category. The applicable score for each MIPS eligible clinician is the higher of either:

(i) A group score based on the measure data for the performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups.

(ii) An individual score based on the measure data for the performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's performance category score.

(2) *Cost scoring for APM Entity groups.* The cost performance category weight is zero percent for APM Entities in MIPS APMs.

(3) *Improvement scoring for APM Entity groups.* For an APM Entity for which CMS calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b).

(4) *Extreme and uncontrollable circumstances.* Beginning with the 2022 MIPS payment year, an APM Entity may submit to CMS an application described at § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(2) requesting reweighting of all four MIPS performance categories and for all MIPS eligible clinicians in the APM Entity group, based on extreme and uncontrollable circumstances.

(i) An APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

(ii) If CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories will be reweighted for the APM Entity group notwithstanding the data submission.

■ 17. Section 414.1320 is amended by revising paragraphs (d) introductory text and (d)(1) and adding paragraph (g) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(d) Beginning with the 2023 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-

based measures in the MIPS final list of quality measures described in § 414.1330(a)(1).

* * * * *

(g) For purposes of the 2024 MIPS payment year and each subsequent MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 18. Section 414.1325 is amended by revising paragraph (c)(1) to read as follows:

§ 414.1325 Data submission requirements.

* * * * *

(c) * * *

(1) For the quality performance category, the direct; login and upload; Medicare Part B claims (beginning with the 2021 MIPS payment year, for small practices only); and for the 2019 through 2023 MIPS payment years, CMS Web Interface (for groups consisting of 25 or more eligible clinicians or a third party intermediary submitting on behalf of a group) submission types.

* * * * *

■ 19. Section 414.1330 is amended by adding paragraphs (b)(4) and (5) to read as follows:

§ 414.1330 Quality performance category.

* * * * *

(b) * * *

(4) 40 percent of a MIPS eligible clinician's final score for the MIPS payment year 2023.

(5) 30 percent of a MIPS eligible clinician's final score for the MIPS payment year 2024 and future years.

■ 20. Section 414.1350 is amended by adding paragraphs (d)(4) and (5) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(d) * * *

(4) 20 percent of the MIPS final score for MIPS payment year 2023.

(5) 30 percent of the MIPS final score for MIPS payment year 2024 and each subsequent MIPS payment year.

■ 21. Section 414.1367 is added to read as follows:

§ 414.1367 APM performance pathway.

(a) *General.* Beginning with the 2023 MIPS payment year, the APM Performance Pathway is a MIPS scoring methodology available to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM.

(b) *Criteria for MIPS APMs.* MIPS APMs are those in which:

(1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation; and

(2) The APM bases payment on quality measures and cost/utilization.

(c) *MIPS performance category scoring in the APM Performance Pathway*—(1) *Quality.* Except as provided in paragraphs (c)(1)(i) and (ii) of this section, the quality performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(1) based on the APM Performance Pathway quality measure set established by CMS through rulemaking for a MIPS payment year.

(i) Each submitted measure that does not have a benchmark or meet the case minimum requirement is excluded from the MIPS eligible clinician, group, or APM Entity group's total measure achievement points and total available measure achievement points.

(ii) Any measure that is identified as topped out is not subject to the scoring cap described at § 414.1380(b)(1)(iv).

(2) *Cost.* The cost performance category weight is zero percent for MIPS eligible clinicians who are scored through the APM Performance Pathway.

(3) *Improvement activities.* The improvement activities performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(3) based on the activities required by the MIPS APM that are included in the MIPS final inventory of improvement activities described in § 414.1355(a) (excluding any such activities that the MIPS eligible clinician, group, or APM Entity group does not perform). MIPS eligible clinicians, groups, or APM Entities may report additional improvement activities in accordance with § 414.1360.

(4) *Promoting interoperability.* The promoting interoperability performance category will be scored for the MIPS eligible clinician, group, or APM Entity as described in § 414.1375.

(d) *APM Performance Pathway performance category weights*—(1) *Performance category weights.* Subject to paragraph (d)(2) of this section, the performance category weights used to calculate the final score for a MIPS eligible clinician, group, or APM Entity reporting through the APM performance Pathway are:

(i) Quality: 50 percent.

(ii) Cost: 0 percent.

(iii) Improvement Activities: 20 percent.

(iv) Promoting Interoperability: 30 percent.

(2) *Reweighting MIPS performance categories.* If CMS determines, in accordance with § 414.1380(c)(2), that a different scoring weight should be assigned to the quality or promoting interoperability performance category, CMS will redistribute the performance category weights as follows:

(i) If CMS reweights the quality performance category to 0 percent: Promoting Interoperability performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to 0 percent: Quality performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(e) *Final score.* The final score is calculated for a MIPS eligible clinician, group, or APM Entity in accordance with § 414.1380(c).

■ 22. Section 414.1370 is amended by revising paragraph (a) to read as follows:

§ 414.1370 APM scoring standard under MIPS.

(a) *General.* For the 2019 through 2022 MIPS payment years, the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS APM.

* * * * *

■ 23. Section 414.1380 is amended—

■ a. By revising paragraph (b)(1)(i) introductory text;

■ b. In paragraph (b)(1)(i)(A)(*1*) by removing ''for the 2019 through 2022 MIPS payment years'' and adding in its place ''for the 2019 through 2023 MIPS payment years'';

■ c. By revising paragraphs (b)(1)(iii);

■ d. In paragraph (b)(1)(v)(A)(*1*)(*ii*) by removing ''For the 2019 through 2022 MIPS payment years'' and adding in its place ''For the 2019 through 2023 MIPS payments years'';

■ e. In paragraph (b)(1)(v)(B)(*1*)(*i*) by removing ''For the 2019 through 2022 MIPS payment years'' and adding in its place ''For the 2019 through 2023 MIPS payment years'';

■ f. In paragraph (b)(1)(vi)(C)(*4*) by removing ''For the 2020 through 2022 MIPS payment years'' and adding in its place ''For the 2020 through 2023 MIPS payment years'';

■ g. By revising paragraph (b)(1)(vii)(A);

■ h. By removing paragraph (b)(1)(viii);
■ i. By revising paragraphs (c)(2)(i)(A)(*4*) and (*5*);
■ j. By adding paragraphs (c)(2)(ii)(E) and (F);
■ k. By revising paragraph (c)(3) introductory text and (c)(3)(iii); and
■ l. By adding paragraph (c)(3)(iv).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(i) *Measure achievement points.* For the 2019 through 2023 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

* * * * *

(iii) *Minimum case requirements.* Except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

* * * * *

(vii) * * *

(A) For each measure that is submitted, if applicable, and impacted by significant changes, performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) For the Promoting Interoperability performance category for the 2021, 2022 and 2023 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*5*) For the Promoting Interoperability performance category for the 2019, 2020, 2021, 2022, and 2023 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(ii) * * *

(E) For the 2023 MIPS payment year:

TABLE 6 TO PARAGRAPH (c)(2)(ii)(E)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	40	20	15	25
No Cost	55	0	15	30
No Promoting Interoperability	65	20	15	0
No Quality	0	20	15	65
No Improvement Activities	55	20	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	80	20	0	0
No Quality and no Improvement Activities	0	20	0	80

(F) For the 2024 MIPS payment year:

TABLE 7 TO PARAGRAPH (c)(2)(ii)(F)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	55	30	15	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

* * * * *

(3) *Complex patient bonus.* For the 2020, 2021, 2022, and 2023 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

* * * * *

(iii) The complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv) of this section.

(iv) For the 2022 MIPS payment year, the complex patient bonus is calculated pursuant to paragraphs (c)(3)(i) and (ii) of this section, and the resulting numerical value is then multiplied by 2.0. The complex patient bonus cannot exceed 10.0.

* * * * *

■ 24. Section 414.1400 is amended—

■ a. By revising paragraphs (a)(2)(i) and (ii) and (a)(4);

■ b. By revising paragraph (b) heading and paragraph (b)(2) introductory text;

■ c. By adding paragraphs (b)(2)(iv) and (v);

■ d. By adding paragraphs (b)(3)(v)(C)(*1*) and (*2*);

■ e. By revising paragraphs (b)(3)(v)(E) and (b)(3)(vi);

■ f. By removing paragraphs (b)(3)(vii)(H) and (L);

■ g. By redesignating paragraphs (b)(3)(vii)(I), (J), (K), (M), and (N) as paragraphs (b)(3)(vii)(H), (I), (J), (K), and (L), respectively;

■ h. By revising paragraph (c) heading;

■ i. By adding paragraphs (c)(2)(iii) and (iv); and

■ j. By revising paragraph (f)(1)(i).

The additions and revisions read as follows:

§ 414.1400 Third party intermediaries.

(a) * * *

(2) * * *

(i) Except as provided under paragraph (a)(2)(ii) of this section, QCDRs, qualified registries, and Health IT vendors must be able to submit data for all of the following MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) For qualified registries and Health IT vendors, QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

(ii) Health IT vendors that do not support MIPS Value Pathways must be able to submit data for at least one of the MIPS performance categories described in paragraphs (a)(2)(i)(A) through (C) of this section.

* * * * *

(4) Third party intermediary approval criteria—

(i) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(A) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(B) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(C) All data must be submitted in the form and manner specified by CMS.

(D) If the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(E) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(F) Prior to discontinuing services to any MIPS eligible clinician, group, or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan.

(ii) The determination of whether to approve an entity as a third party intermediary for a MIPS payment year may take into account:

(A) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and

(B) Whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician.

(iii) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

* * * * *

(b) *QCDRs.* * * *

(2) *QCDR conditions for approval.* In addition to the other requirements in this section, the criteria for an entity to be approved as a QCDR include the following:

* * * * *

(iv) Beginning with the 2023 payment year, the QCDR must conduct annual data validation audits in accordance with this paragraph (b)(2)(iv).

(A) The QCDR must conduct data validation for the payment year prior to submitting any data for that payment

year to CMS for purposes of the MIPS program.

(B) The QCDR must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The QCDR must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.

(D) The QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The QCDR shall conduct each data validation audit using a sampling methodology that meets the following requirements:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each QCDR data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only the MIPS quality measures and QCDR measures, as applicable, that are relevant to the performance period will be used for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall data deficiencies or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or error, and, how and when each deficiency or data error type was corrected.

(v) Beginning with the 2023 MIPS payment year, the QCDR must conduct targeted audits in accordance with this this paragraph (b)(2)(v).

(A) If a data validation audit under paragraph (b)(2)(iv) of this section identifies one or more deficiency or data error, the QCDR must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The QCDR must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The QCDR must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(2)(iv)(E) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

(3) * * *

(v) * * *

(C) * * *

(*1*) To be approved for the 2024 MIPS payment year, a QCDR measure must be face valid. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

(*2*) To be included in an MIPS Value Pathway for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested.

* * * * *

(E) Beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

(vi) Beginning with the 2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

* * * * *

(c) *Qualified registries.* * * *

(2) * * *

(iii) Beginning with the 2023 payment year, the qualified registry must conduct annual data validation audits in accordance with this paragraph (c)(2)(iii).

(A) The qualified registry must conduct their data validation audits prior to submitting any data to CMS for purposes of the MIPS program.

(B) The qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The qualified registry must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.

(D) The qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The qualified registry shall conduct each data validation audit using a sampling methodology that meets the following:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the qualified registry may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each qualified registry data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only MIPS quality measures and qualified registry measures that are relevant to the performance period will be utilized for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, how and when each deficiency or data error type was corrected.

(iv) Beginning with the 2023 MIPS payment year, the qualified registry must conduct targeted audits in accordance with this paragraph (c)(2)(iv).

(A) If a data validation audit under paragraph (c)(2)(iii) of this section identifies one or more deficiency or data error, the qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraphs (c)(2)(iii)(E)(*1*) and (*2*) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, how and when each deficiency or data error type was corrected.

* * * * *

(f) * * *

(1) * * *

(i) Require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the non-compliance.

(B) The impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program.

(C) The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.

(D) The detailed timeline for achieving compliance with the applicable requirements.

* * * * *

■ 25. Section 414.1435 is amended by revising paragraph (c)(1) to read as follows:

§ 414.1435 Qualifying APM participant determination: Medicare option.

* * * * *

(c) * * *

(1) Attributed beneficiaries are determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology except as set forth in this paragraph (c)(1).

(i) Beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

(ii) [Reserved]

* * * * *

■ 26. Section 414.1450 is amended by revising paragraphs (b)(1) and (c) to read as follows:

§ 414.1450 APM incentive payment.

* * * * *

(b) * * *

(1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment.

* * * * *

(c) *APM Incentive Payment recipient.* CMS will pay the APM Incentive Payment amount for a payment year to a solvent TIN or TINs associated with the QP identified at a specific step in the following hierarchy. If no TIN or TINs with which the QP has an association can be identified at a step, CMS will move to the next and successive steps listed in paragraphs (c)(1) through (8) of this section until CMS identifies a TIN or TINs with which the QP is associated, and to which CMS will make the APM Incentive Payment.

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by November 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

* * * * *

■ 27. Section 414.1455 is revised to read as follows:

§ 414.1455 Limitation on review.

(a) There is no right to administrative or judicial review under sections 1869, 1878, or otherwise, of the Act of the following:

(1) The determination that an eligible clinician is a QP or Partial QP under § 414.1425.

(2) The determination of the amount of the APM Incentive Payment under § 414.1450, including any estimation as part of such determination.

(b)(1) An eligible clinician or APM Entity may request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List.

(2) If CMS determines that there was such a clerical error, if the QP determination for the eligible clinician would have been made at the APM Entity level under § 414.1425(b)(1), CMS will assign to the eligible clinician the most favorable QP status that was determined at the APM Entity level on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity.

(3) The process for targeted review is as follows:

(i) An eligible clinician or APM Entity may submit a request for targeted review.

(ii) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins with the publication of MIPS performance feedback as described at § 414.1385(a)(2). The targeted review request submission period may be extended as specified by CMS.

(iii) All requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

(iv) A request for targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted during the targeted review request submission period; or the request is outside the scope of targeted review specified in this section. If the targeted review request is denied, CMS will make no changes to the QP status of the eligible clinician for whom targeted review was requested.

(v) CMS will respond to each timely submitted request for targeted review.

(vi) A request for targeted review may include additional information in support of the request at the time it is submitted. CMS may also request additional information from the requestor. If CMS requests additional information relating to the eligible clinician or the APM Entity group that is the subject of a request for targeted review, responsive information must be provided and received by CMS within 30 days of the request. If CMS does not receive a timely response to a request for additional information, CMS may make a final decision on the targeted review request based on the information available.

(vii) If targeted review requests reveal a pattern of CMS error with impacts that extend beyond the scope of eligible clinicians or APM Entities that submitted such targeted review requests, CMS may adjust the QP status of other affected eligible clinicians as provided in paragraph (b)(2) of this section.

(viii) Decisions on a targeted review request are final, and not subject to any further administrative or judicial review in accordance with paragraph (a) of this section.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 28. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 29. Section 415.172 is amended by revising paragraph (a) introductory text, (a)(2), and (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. In residency training sites that are located outside a metropolitan statistical area, physician fee schedule payment may also be made if a teaching physician is present during the key portion of the service, including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought. For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, if a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made if a teaching physician is present during the key portion of the service including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought.

* * * * *

(2) In the case of evaluation and management services, except as otherwise provided in this paragraph (a)(2), the teaching physician must be present in person during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(i) In residency training sites that are located outside of a metropolitan statistical area, the teaching physician may be present through audio/video real-time communications technology during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(ii) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the teaching physician may be present through audio/video real-time communications technology during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(b) *Documentation.* Except as otherwise provided in this paragraph (b), except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), §§ 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document that the teaching physician was present at the time the service (including a Medicare telehealth service) is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

(1) In residency training sites that are located outside of a metropolitan statistical area only, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and

certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

(2) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

* * * * *

■ 30. Section 415.174 is amended by revising paragraph (c) and adding paragraph (d) to read as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

* * * * *

(c) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the requirements in paragraph (a)(3) of this section for a teaching physician to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through audio/video real-time communications technology.

(d) In residency training sites that are located outside of a metropolitan statistical area only, the requirements in paragraph (a)(3) of this section for a teaching physician to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through audio/video real-time communications technology.

■ 31. Section 415.180 is revised to read as follows:

§ 415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule.* Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident.

(1) In residency training sites that are located outside of a metropolitan statistical area only, physician fee schedule payment may also be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the interpretation of review of the diagnostic radiology test.

(2) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, physician fee schedule payment may also be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the interpretation or review of the diagnostic radiology or diagnostic test.

(b) [Reserved]

■ 32. Section 415.184 is revised to read as follows:

§ 415.184 Psychiatric services.

(a) Physician fee schedule payment is made for psychiatric services furnished under an approved GME program if the requirements of §§ 415.170 and 415.172 are met, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

(b) In residency training sites that are located outside of a metropolitan statistical area, the requirement for the presence of the teaching physician during the service in which a resident is involved may be met through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the service.

(c) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the requirement for the presence of the teaching physician during the service in which a resident is involved may also be met through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the service.

■ 33. Section 415.208 is amended by revising paragraph (b) heading and paragraph (b)(2) introductory text to read as follows:

§ 415.208 Services of moonlighting residents.

* * * * *

(b) *Services in teaching hospitals.*

* * *

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i) through (iii) of this section are met. The services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i) through (iii) of this section are met. The medical record must include documentation to demonstrate in each case that these criteria are satisfied.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 34. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 35. Section 423.160 is amended by adding paragraph (a)(5) to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) On January 1, 2021, prescribers must, except in circumstances in which the Secretary waives the requirement, conduct all prescribing for all Schedule II, III, IV, and V controlled substances electronically using the applicable standards in paragraph (b) of this section. Compliance actions against those not in compliance with this requirement will commence January 1, 2022.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 36. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 37. Section 424.67 is amended by—

■ a. Revising paragraphs (b)(1) introductory text, (b)(1)(ii), (b)(2) and (3), and (b)(5) introductory text;

■ b. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g), respectively;

■ c. Adding new paragraph (c); and

■ d. Revising newly redesignated paragraph (e)(2)(i).

The revisions and additions read as follows:

§ 424.67 Enrollment requirements for opioid treatment programs (OTP).

* * * * *

(b) * * *

(1) Fully complete and submit, as applicable, the Form CMS–855A or Form CMS–855B application (or their successor applications) and any applicable supplement or attachment thereto to its applicable Medicare contractor. This includes, but is not limited to, the following:

* * * * *

(ii) Certifying via the Form CMS–855A or Form CMS–855B (as applicable) and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in paragraphs (b) and (e) of this section.

(2) Comply with the application fee requirements in § 424.514. (This includes OTPs enrolling under the circumstances described in paragraph (c)(2) of this section.)

(3)(i) Except as stated in paragraph (b)(3)(ii) of this section, successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c).

(ii) For currently enrolled OTPs that are changing their OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, successfully complete the limited level of categorical screening under § 424.518(a) if the OTP has already completed, as applicable, the moderate or high level of categorical screening under § 424.518(b) or (c), respectively.

* * * * *

(5) Report on the Form CMS–855A or Form CMS–855B (as applicable) and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. Such individuals include, but are not limited to, the following:

* * * * *

(c) *Clarification of required enrollment forms.* (1) An OTP may only be enrolled as an OTP via the Form CMS–855A or Form CMS–855B but not both.

(2) If a currently enrolled OTP is changing its OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, the effective date of billing that was established for the OTP's prior enrollment under §§ 424.520(d) and 424.521(a) is applied to the OTP's new enrollment.

* * * * *

(e) * * *

(2) * * *

(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement or standard in this section, including, but not limited to, the OTP standards in paragraphs (b)(6) and (e)(1) of this section.

* * * * *

■ 38. Section 424.518 is amended by redesignating paragraphs (a)(1)(xii) through (xvii) as paragraphs (a)(1)(xiii) through (xviii) and adding a new paragraph (a)(1)(xii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(a) * * *

(1) * * *

(xii) Opioid treatment programs (if § 424.67(b)(3)(ii) applies).

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 39. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 40. Section 425.100 is amended by revising paragraph (b) to read as follows:

§ 425.100 General.

* * * * *

(b) An ACO is eligible to receive payments for shared savings under subpart G of this part if all of the following conditions are met:

(1) The ACO meets or exceeds the applicable minimum savings rate established under § 425.604, § 425.605, § 425.606, § 425.609, or § 425.610.

(2) The ACO meets the minimum quality performance standards established under § 425.500 (for performance years or a performance period beginning on or before January 1, 2020), or under the quality performance standard established under § 425.512 (for performance years beginning on or after January 1, 2021).

(3) The ACO otherwise maintains its eligibility to participate in the Shared Savings Program under this part.

* * * * *

§ 425.112 [Amended]

■ 41. Section 425.112 is amended in paragraph (b)(2)(i) by removing the reference ''§ 425.500'' and adding in its place the references ''§ 425.500 or § 425.510, as applicable''.

§ 425.200 [Amended]

■ 42. Section 425.200 is amended in paragraph (d) by removing the reference ''§ 425.500(c)'' and adding in its place the references ''§ 425.500(c) or § 425.510, as applicable''.

■ 43. Section 425.204 is amended by—

■ a. Revising paragraphs (f)(3)(i) through (iv);

■ b. Adding paragraph (f)(3)(v); and

■ c. Revising paragraphs (f)(4)(iv), (f)(5), and (f)(6)(ii) introductory text.

The revisions and addition read as follows:

§ 425.204 Content of the application.

* * * * *

(f) * * *

(3) * * *

(i) An ACO participating in Track 2 must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC track or the ENHANCED track must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iii) An ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the

adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to, a two-sided model, Level C, Level D, or Level E of the BASIC track, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iv) An ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the ACO, provided that the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section, and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(v) As part of its application, a re-entering ACO must submit documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the re-entering ACO, provided that the ACO is the same legal entity as an ACO that previously participated in the program, and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(4) * * *

(iv)(A) In the case of an ACO that has submitted a request to enter a new participation agreement for an agreement period starting on or after January 1, 2022 and is a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program: If the ACO wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to at least the amount calculated by CMS in accordance with paragraph (f)(4)(ii) of this section.

(B) Under the following circumstances, an ACO that renewed its participation agreement for an agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism.

(*1*) The ACO elected to continue to use its existing repayment mechanism for the agreement period beginning on July 1, 2019, or January 1, 2020, and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated at the time of renewal application according to paragraph (f)(4)(ii) of this section.

(*2*) The repayment mechanism amount for performance year 2021, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(*3*) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(iv)(B). The ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

(5) After the repayment mechanism has been used to repay any portion of shared losses owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days. The resulting amount available through the repayment mechanism must be at least the amount specified by CMS in accordance with paragraph (f)(4) of this section.

(6) * * *

(ii) For a renewing ACO, or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the existing repayment mechanism must be amended to meet one of the following criteria.

* * * * *

■ 44. Section 425.224 is amended by revising paragraph (b)(1)(ii)(A) to read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) Whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

* * * * *

§ 425.302 [Amended]

■ 45. Section 425.302 is amended in paragraph (a)(1) by removing the reference ''§ 425.500'' and adding in its place the references ''§ 425.500 or § 425.510, as applicable''.

■ 46. Section 425.316 is amended by revising paragraph (c) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under § 425.500 or § 425.512. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, CMS will take the following actions:

(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* (i) The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(ii) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standard in the following year, the agreement will be terminated.

(iii) An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

(2) *For performance years beginning on or after January 1, 2021.* (i) If the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may

immediately terminate the ACO's participation agreement under § 425.218.

(ii) CMS will terminate an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.

(D) A renewing ACO or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

* * * * *

■ 47. Section 425.400 is amended by—

■ a. Revising paragraph (c)(1)(iv) introductory text;

■ b. Adding paragraph (c)(1)(v); and

■ c. Revising paragraph (c)(2).

The revisions and addition read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(iv) For performance years (or a performance period) during 2019, and performance year 2020 as follows:

* * * * *

(v) For the performance year starting on January 1, 2021, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(v)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99439 (code for non-complex chronic care management).

(*9*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*11*) 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*12*) 99495 and 99496 (codes for transitional care management services).

(*13*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 (code for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G2214 (code for psychiatric collaborative care model).

(2)(i) When the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

(A) CPT codes:

(*1*) 99421, 99422, and 99423 (codes for online digital evaluation and management services).

(*2*) 99441, 99442, and 99443 (codes for telephone evaluation and management services).

(B) HCPCS codes:

(*1*) G2010 (code for the remote evaluation of patient video/images).

(*2*) G2012 (code for virtual check-in).

(ii) The additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

■ 48. Section 425.500 is amended by revising the section heading and paragraph (d) to read as follows:

§ 425.500 Measures to assess the quality of care furnished by an ACO for performance years (or a performance period) beginning on or before January 1, 2020.

* * * * *

(d) *Patient experience of care survey.* (1) For performance years (or a performance period) beginning in 2014 through 2019, ACOs must select a CMS-certified vendor to administer the survey and report the results accordingly.

(2) For performance year 2020, CMS waives the CAHPS for ACOs reporting requirement and will assign all ACOs automatic credit for the CAHPS for ACOs survey measures.

* * * * *

■ 49. Section 425.502 is amended by revising the section heading to read as follows:

§ 425.502 Calculating the ACO quality performance score for performance years (or a performance period) beginning on or before January 1, 2020.

* * * * *

■ 50. Section 425.508 is amended by revising the paragraph (a) heading and adding paragraph (b) to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

(a) *For performance years (or a performance period) beginning in 2017–2020.* * * *

(b) *For performance years beginning on or after January 1, 2021.* ACOs must submit the quality data via the Alternative Payment Model Performance Pathway (APP) established under § 414.1367 of this chapter, to satisfactorily report on behalf of the

eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

■ 51. Section 425.510 is added to subpart F to read as follows:

§ 425.510 Application of the Alternative Payment Model Performance Pathway (APP) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.

(a) *General.* (1) CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible to receive shared savings.

(2) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(b) *Quality reporting.* ACOs must report quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS.

(c) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO under paragraph (b) of this section according to § 414.1390 of this chapter.

■ 52. Section 425.512 is added to subpart F to read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) *Establishing a quality performance standard*—(1) *Overall standard.* The quality performance standard is the overall standard the ACO must meet in order to be eligible to receive shared savings for a performance year. An ACO will not qualify to share in savings in any year it fails to meet the quality performance standard.

(2) *For performance year 2022 and subsequent performance years.* For the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO meets the data completeness requirement at § 414.1340 of this chapter and case minimum requirement at § 414.1380 of this chapter on the three measures it is actively required to report and fields a CAHPS for MIPS survey via the APP, the ACO will meet the quality performance standard.

(3) *For performance years 2021 and 2022*—(i) *Designation of quality performance standard.* For all ACOs, except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) *For performance year 2021.* If an ACO does not report any of the ten CMS Web Interface measures or any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.

(iii) *For performance year 2022.* If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.

(4) *For performance years 2023 and subsequent performance years.* (i) For all ACOs, except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.

(b) *Extreme and uncontrollable circumstances.* For performance year 2021 and subsequent performance years, including the applicable quality data reporting period for the performance year, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraph (a) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination, CMS uses the quarter four list of assigned beneficiaries.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (b)(1) of this section, CMS calculates the ACO's quality score as follows:

(i) For performance years 2021 and 2022, the ACO's minimum quality performance score is set to the equivalent of the 30th percentile MIPS Quality performance category score for the relevant performance year as determined under paragraph (a)(3) of this section.

(ii) For performance year 2023 and subsequent performance years, the ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS Quality performance category score for the relevant performance year as determined under paragraph (a)(4) of this section.

(3) If the ACO reports quality data via the APP and meets data completeness and case minimum requirements:

(i) For performance years 2021 and 2022, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score for the relevant performance year.

(ii) For performance year 2023 and subsequent performance years, CMS will use the higher of the ACO's quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score for the relevant performance year.

(4) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(5) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

■ 53. Section 425.600 is amended by revising paragraph (f)(4)(i) to read as follows:

§ 425.600 Selection of risk model.

* * * * *

(f) * * *

(4) * * *

(i) The quality performance standard as described in § 425.502(a) or § 425.512(a), as applicable.

* * * * *

■ 54. Section 425.601 is amended by revising paragraphs (a)(9) and (f)(5)(iv) to read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years.

(a) * * *

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph (a)(8) of this section, according to the ACO's assigned beneficiaries for BY3.

* * * * *

(f) * * *

(5) * * *

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in paragraph (a)(9) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) and (2) of this section used in calculating the adjustment under either paragraph (a)(8) or (e) of this section.

* * * * *

■ 55. Section 425.602 is amended by revising paragraph (a)(8) to read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period beginning on or before January 1, 2018.

(a) * * *

(8) The ACO's benchmark is adjusted for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b) and for a change to the beneficiary assignment methodology specified in subpart E of this part, as applicable, to take into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

* * * * *

■ 56. Section 425.603 is amended by revising paragraphs (c)(8) and (c)(9)(ii)(B)(*4*)(*iv*) to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period beginning on or before January 1, 2019.

* * * * *

(c) * * *

(8) The ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph (c)(9) of this section, according to the ACO's assigned beneficiaries for BY3.

(9) * * *

(ii) * * *

(B) * * *

(*4*) * * *

(*iv*) If CMS adjusts the ACO's benchmark, as specified in paragraph (c)(8) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage used in calculating the adjustment in paragraphs (c)(9)(ii)(B)(*1*) and (*2*) of this section.

* * * * *

■ 57. Section 425.604 is amended by revising paragraphs (c) and (d) to read as follows:

§ 425.604 Calculation of savings under the one-sided model.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* In order to qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For the performance year beginning on January 1, 2021.* To qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For the performance year beginning on January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under Track 1 will receive a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

■ 58. Section 425.605 is amended by revising paragraphs (c), (d)(1)(i)(A), (d)(1)(ii)(A), (d)(1)(iii)(A), (d)(1)(iv)(A), and (d)(1)(v)(A) to read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) * * *

(1) * * *

(i) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or*

before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

* * * * *

(ii) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

* * * * *

(iii) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

* * * * *

(iv) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

* * * * *

(v) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

* * * * *

■ 59. Section 425.606 is amended by revising paragraphs (c), (d), and (f) to read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For the performance year beginning on January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of up to 60 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For the performance year beginning on January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of 60 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

(f) *Shared loss rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 60 percent; and

(ii) May not be less than 40 percent.

(2) *For the performance year beginning on January 1, 2021.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS Quality performance category points

earned divided by the total MIPS Quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section and 60 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 60 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in § 425.512, the shared loss rate is 60 percent.

* * * * *

■ 60. Section 425.610 is amended by revising paragraphs (c), (d), and (f) to read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of up to 75 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of 75 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

(f) *Shared loss rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 75 percent; and

(ii) May not be less than 40 percent.

(2) *For performance years beginning on or after January 1, 2021.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section, and 75 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in § 425.512, the shared loss rate is 75 percent.

* * * * *

■ 61. Section 425.611 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 425.611 Adjustments to Shared Savings Program calculations to address the COVID–19 pandemic.

* * * * *

(b) * * *

(1) * * *

(ii) Discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the Public Health Emergency as defined in § 400.200 of this chapter.

* * * * *

§ 425.800 [Amended]

■ 62. Section 425.800 is amended—

■ a. In paragraph (a)(1) by removing the references ''§ 425.500 and § 425.502'' and adding in its place the references ''§§ 425.500, 425.502, 425.510, and 425.512;''

■ b. In paragraph (a)(2) by removing the reference ''§ 425.502'' and adding in its place the references ''§ 425.502 or § 425.512, as applicable''; and

■ c. In paragraph (a)(6) by removing the reference ''§ 425.502'' and adding in its place the references ''§ 425.502 or § 425.512, as applicable''.

Dated: November 18, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 23, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

APPENDIX 1: MIPS QUALITY MEASURES

NOTE: Except as otherwise noted in this final rule, previously finalized measures and specialty measure sets will continue to apply for the 2023 MIPS payment year and future years. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF # / eCQM NQF #.

TABLE Group A: New Quality Measures Finalized for the 2023 MIPS Payment Year and Future Years

A.1. Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	479
Description:	This measure is a re-specified version of the measure, "Risk-adjusted readmission rate (RARR) of unplanned readmission within 30 days of hospital discharge for any condition" (NQF 1789), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to MIPS participating clinician groups and assesses each group's readmission rate. The measure comprises a single summary score, derived from the results of five models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): medicine, surgery/gynecology, cardio-respiratory, cardiovascular, and neurology.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is unplanned all-cause 30-day readmission. Readmission is defined as a subsequent inpatient admission to any acute care facility which occurs within 30 days of the discharge date of an eligible index admission. Any readmission is eligible to be counted as an outcome, except those that are considered planned. To align with data years used, the planned readmission algorithm version 4.0 was used to classify readmissions as planned or unplanned.
Denominator:	Patients eligible for inclusion in the measure have an index admission hospitalization to which the readmission outcome is attributed and includes admissions for patients: Enrolled in Medicare Fee-For-Service (FFS) Part A for the 12 months prior to the date of admission; Aged 65 or over; Discharged alive from a non-federal short-term acute care hospital; and, Not transferred to another acute care facility.
Exclusions:	1. Patients discharged against medical advice (AMA) are excluded. 2. Admissions for patients to a PPS-exempt cancer hospital are excluded. 3. Admissions primarily for medical treatment of cancer are excluded. 4. Admissions primarily for psychiatric disease are excluded. 5. Admissions for "rehabilitation care; fitting of prostheses and adjustment devices" (CCS 254) are excluded. 6. Admissions where patient cannot be attributed to a clinician group.
Measure Type:	Outcome
Measure Domain:	Communication and Care Coordination (section 1848(s)(1)(B)(iii) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Measure Implementation:	MIPS eligible groups with at least 16 clinicians / 200 case minimum / 1 year performance period (January 1st – December 31st)
Rationale:	This risk-adjusted administrative claims measure was proposed to address unplanned readmissions at the physician group level of Medicare aged > 65 patients. This measure is a re-specified version of the hospital-level measure, "Hospital-Wide All-Cause, Unplanned Readmission Measure" (NQF #1789), which has been in the MIPS program since 2017. In the event we did not finalize this measure, we would have maintained the current measure Q458: All-Cause Hospital Readmission. The re-specification of this measure promotes a systems-level approach by clinicians and focus on high-risk conditions, such as COPD and heart failure. The measure was evaluated by the MAP and was conditionally supported pending NQF endorsement. While we agreed with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required in section 1848(q)(2)(D)(v) of the Act. A risk-adjusted readmission rate of 15.3 percent at the physician group level was provided by the measure developer. The readmission rate indicates a substantial need to reduce the expected rate and variation of rates across eligible physician groups. Physician groups have the capability to influence unplanned readmission outcomes by appropriate medication reconciliation at discharge, reduction of infection risk, and ensuring proper outpatient follow-up. As an administrative claims measure, there is no separate reporting burden. To maintain continuity with the existing measure Q458: All-Cause Hospital Readmission, the case minimum will remain at 200 cases for consistency in implementation. For 2023 payment determination, the performance period will include administrative claims from January 1, 2021 to December 31, 2021. For further information regarding the implementation of this measure, please see section IV.A.3.c.(1)(e)(i) of this final rule. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.
Comment: One commenter appreciated this measure as a change to the All-Cause Readmissions measure (Q458) to better align with a system-level approach so that patient care can be focused more on high risk conditions. A second commenter supported this new measure, stating that it improves upon the existing readmissions measure as it targets unplanned readmissions to the hospital.	

Category	Description

Response: We thank the commenters for supporting the new HWR measure in the MIPS program.

Comment: One commenter appreciated the measure steward's efforts to provide additional justification for attribution of the Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) measure to the three types of clinician groups, but believed the evidence falls short of demonstrating clear attribution to decreased readmission rates. In addition, the commenter believed the reliability levels for the cardiorespiratory and cardiovascular cohorts continue to be too low for acceptable use. In addition, prior attempts to reduce readmission rates for the heart failure population was associated with a reduction in the rate of readmissions, but also an increase in the rate of death among Medicare patients hospitalized with heart failure. The commenter requested that CMS ensure these issues are considered as the measure continues through development and the endorsement process at NQF.

Response: While the existing literature on the association between clinicians and patient outcomes may be sparse, the Technical Expert Panel (TEP) and clinical consultants, most of whom are clinicians themselves, strongly supported the attribution model and identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions; and therefore, together, can reduce the risk of readmission. Clinicians are critical contributors to quality improvement, whether as change agents and influencers of health systems or key stakeholders whose acceptance is required for successful or long-lasting improvements. The case minimum will align with that of measure Q458 for consistency in implementation so that only eligible clinician groups with at least 200 cases will receive a measure score. This aligns with feedback received from the public and NQF Admissions/Readmissions committee as well as empiric analyses demonstrating that the minimum case count of 200 cases produces exceptionally reliable measure scores for eligible clinician groups. Using a minimum case count of 200 cases, measure reliability testing conducted by the developers indicated substantial signal to noise reliability across all five specialty cohorts, ranging from 0.82 for surgical to 0.92 for neurology (Adams et al, 2010). Specifically, when limiting to clinician groups with at least 200 cases, the cardiorespiratory and cardiovascular specialty cohorts in question had mean signal to noise reliability scores of 0.89 and 0.88, respectively, indicating substantial reliability (Adams et al, 2010).

We are aware of the literature that suggested an inverse association between 30-day readmission and 30-day mortality for heart failure admissions (Gupta et al. 2018). However, the paper was based on 416 hospitals, which is a small proportion of hospitals participating in the Hospital Readmission Reduction Program (HRRP), and focuses on the temporal association between the HRRP's introduction and an increase in 30-day and one-year mortality rates for heart failure discharges. We continuously monitor the literature related to the impact and unintended consequences of measurement and CMS programs and found the evidence that readmission measurement has increased heart failure mortality as inconclusive. The Medicare Payment Advisory Commission (MedPAC 2018) completed an analysis on readmission measurement within the HRRP and found no negative effect on mortality. Furthermore, literature using the complete sample of over 4,000 hospitals participating in HRRP found that the decline in readmission was not associated with an increase in heart failure mortality and that lowering readmissions actually tends to also lower mortality (Kera et al 2018 and Dharmarajan et al. 2017). The observed increase in mortality in Gupta et al. (2018) may be due to a decline in admission rates, resulting in patients that are admitted presenting with complex comorbidities and a higher risk of death (Dharmarajan et al. 2017, Krumholz et al. 2015, MedPAC 2018). Given the importance of this potential issue on patient outcomes, we also commissioned an independent group to investigate whether there have been increases in mortality rates after HRRP implementation. We found through this investigation that no sufficient evidence exists to suggest that mortality has increased because of HRRP measurement. We are committed to continuing to monitor trends in readmission and mortality rates through annual measure reevaluation and surveillance tasks.

Comment: One commenter stated that though unlikely, based on the case minimum, this new measure could apply to large radiation oncology or multidisciplinary groups. However, the commenter worried that the attribution methodology will unfairly target radiation oncologists, who do not perform primary care services. CMS finalized specialty exclusions under the Total Per Capita Cost (TPCC) Measure in the 2020 PFS final rule that the TPCC measure is more accurately applied to clinicians who provide primary care services. Under the TPCC, attributed episodes of care are excluded if they are performed by clinicians who (i) frequently perform non-primary care services (for example, global surgery, chemotherapy, anesthesia, radiation therapy) or (ii) are in specialties unlikely to be responsible for providing primary care to a beneficiary (for example, podiatry, dermatology, optometry, ophthalmology). The commenter recommended that CMS apply the same specialty exclusions to the Hospital-Wide, All-Cause Unplanned Readmission claims measure.

Response: There are several exclusion criteria applied to the measure population ("starting cohort"), which include: (1) Admissions for patients to a PPS-exempt cancer hospital; (2) Admissions primarily for medical treatment of cancer; (3) Admissions for "rehabilitation care; fitting of prostheses and adjustment devices;" and (4) Admissions where patient cannot be attributed to a clinician group. Additionally, the measure is risk adjusted to account for differences in patient demographics and clinical characteristics across hospitals. These clinical characteristics may not be related to the quality of care; however, they could impact outcomes for patients. Given the wide variety of discharge diagnosis condition categories, the measure is adjusted for both case mix differences (clinical status of the patient, accounted for by adjusting for comorbidities), as well as service mix differences (the types of conditions/procedures, accounted for by adjusting for the principal discharge diagnosis condition category). Adjustments for case mix differences among clinicians are made by risk-adjusting for patients' comorbid conditions that are identified during inpatient episodes of care for the 12 months prior to the index admission in addition to those present at the index admission. Finally, the intent of the measure is to incentivize coordinated and collaborative care across specialties for a wide variety of patients to reduce unplanned readmissions; radiation oncologists may be able to contribute to optimal care. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter opposed inclusion of this measure in MIPS, citing their primary concern is the risk of unintended consequences because it does not adequately consider the competing risk of mortality. Providers with higher mortality rates for more severely ill patients could appear to be providing better quality care. Concerns have been raised in multiple peer reviewed publications about the possible association between incentives to reduce admission and increased mortality rates. It is also unclear whether hospital readmission rates truly reflect the quality of care for all patient populations and whether incentivizing lower readmissions could potentially exacerbate disparities in care.

The commenter suggested that CMS consider a measure such as risk-adjusted home time, which, if carefully designed, might better balance the competing risks of readmission and mortality, and mitigate some of these concerns. CMS may also want to consider the additional recommendations for improving on readmission measures and reducing the risk of potential inequities and unintended consequences. Lastly, the commenter noted this measure was more appropriate to attribute at the ACO level only due to better oversight and care coordination to influence performance.

Response: Researchers have conducted considerable investigation of potential unintended consequences since the implementation of the readmission measures within HRRP. More specifically, the relationship between the implementation of the AMI, heart failure, and pneumonia readmission measures in the HRRP and subsequent trends in their respective AMI, heart failure, and pneumonia mortality rates has been studied. We continuously monitor the literature related to the impact and unintended consequences of measurement and CMS programs and found the evidence that readmission measurement has increased mortality rates as inconclusive. The Medicare Payment Advisory Commission (MedPAC 2018) completed an analysis on readmission measurement within the HRRP and found no negative effect on mortality. MedPAC's 2018 report confirms that the readmission declines have occurred without clear adverse consequences and concluded that mortality rates do not seem to be increasing in relation to HRRP. In fact, for most HRRP conditions, observed mortality declined after HRRP was implemented, while mortality increased for non-HRRP measured conditions. Risk-adjusted mortality rates

Category	Description
	declined for AMI, pneumonia, and heart failure from 2010 to 2016. Furthermore, the literature demonstrates that there is no evidence for increased inpatient or post-discharge mortality that is directly associated with the timing of the HRRP. In one study, authors examined the rates of readmission and mortality for Medicare patients with heart failure and found that the decline in readmission associated with HRRP was not associated with increase in mortality (Khera et al, 2018). In a second study, the authors found that hospitals lowering readmissions tended to lower mortality (Dharmarajan et al, 2017). Given the importance of this potential issue on patient outcomes, we also commissioned an independent group to investigate whether there have been increases in mortality rates after HRRP implementation. We found through this investigation that no sufficient evidence exists to suggest that mortality has increased because of HRRP measurement. We are committed to continuing to monitor trends in readmission and mortality rates through annual measure reevaluation and surveillance tasks. The measure is risk adjusted to account for differences in patient demographics and clinical characteristics across hospitals. These clinical characteristics may not be related to the quality of care; however, they could impact outcomes for patients. Given the wide variety of discharge diagnosis condition categories, the measure is adjusted for both case mix differences (clinical status of the patient, accounted for by adjusting for comorbidities), as well as service mix differences (the types of conditions/procedures, accounted for by adjusting for the principal discharge diagnosis condition category). Adjustments for case mix differences among clinicians are made by risk-adjusting for patients' comorbid conditions that are identified during inpatient episodes of care for the 12 months prior to the index admission in addition to those present at the index admission. The measure is not risk-adjusted for social risk factors. Measure testing that evaluated the effects of adjusting for social risk factors revealed, after adjustment for clinical factors, a high correlation of 0.99 between unadjusted and adjusted scores as well as a minimal impact on measure scores. There is, in fact, a risk-standardized all-condition readmission measure for accountable care organizations (ACOs) with specifications that are also re-specified from and harmonized with the Hospital-Wide All-Condition 30-Day Risk-Standardized Readmission measure within the Inpatient Quality Reporting (IQR) Program. Introducing hospital-wide readmission measurement within MIPS fills an important gap by creating a mechanism for shared accountability across health providers for readmitted patients and the testing demonstrated meaningful variation in performance across MIPS eligible clinician groups. Additionally, this measure provides greater information and transparency for clinicians and patients to continue to drive improved patient care quality and positive outcomes. **Comment:** Several commenters opposed the addition of this measure for the 2021 performance year. Clinicians and group practices need stability now more than ever, and noted this is not the time to add new metrics, particularly to a category that groups are familiar with already. The commenter expressed significant concerns around administrative claims measures. While CMS asserts these measures do not increase reporting burden since they are calculated on clinicians' behalf, it takes time to study the measures themselves, understand how clinicians are evaluated, and determine how (or if) clinicians can influence performance. With registry or EHR reporting, clinicians can receive real time feedback on measure performance and evaluate whether changes are needed to facilitate improvement. Claims-based measures do not offer the same opportunity, which makes it difficult to improve performance or drive meaningful change. **Response:** For over a decade, readmission after discharge has been a concern both from an aspect of quality and resources, culminating in a national effort to address rates of readmissions for all patients, regardless of age and condition. While we can appreciate the desire for stability, we believe that the Hospital-Wide Readmission measure is a more robust measure as it is based upon the original hospital-level measure has been most rigorously tested and vetted. As an Administrative Claims measure, there is no burden to the clinician regarding collection and scoring. Real-time feedback is not a guaranteed aspect of the eCQMs Specifications or the MIPS CQMs Specifications collection type, but may be a service provided, for example, by a vendor. While this collection type does not provide real-time feedback, CMS supplies eligible clinicians and eligible clinician groups with confidential reports that provide information on measure performance, including patient-level data, to help drive quality improvement. In addition, since they utilize claims data submitted for payment purposes, they provide data elements that are validated through our monitoring and auditing processes and introduce no burden collection of vital information to help drive quality care. **Comment:** One commenter did not support the All-Cause Readmission measure, Q458, because it said it was not suitable for attribution at the clinician or group level. When the newer version of the measure was submitted for NQF consideration (HWR measure), a number of professional organizations disapproved of applying the measure at either the individual clinician level or group practice level. **Response:** This measure is a re-specification of measure Q458 currently within the MIPS program, which attributes outcomes solely to the primary care physician that provides the plurality of care during the measurement period. However, the primary care physician may not be the clinician with opportunity to impact readmissions. The intent of this measure is to improve upon the attribution of the current ACR measure and incentivize collaboration of care across inpatient and outpatient settings by considering shared attribution to up to three eligible clinician groups that provide care for patients inside and outside of the hospital and are therefore in position to influence patient risk of readmission. The TEP and clinical consultants, most of whom are clinicians themselves, supported the attribution model and identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions. The primary inpatient clinician is responsible for the medical care provided during the admission, referring patients to inpatient specialists and prescribing medications. The delivery of their care during the hospital admission can influence whether the patient returns with unresolved medical issues or side effects from inappropriate medication or dosage. The discharge clinician is responsible for preparing the patient for discharge, including determining the patient is well enough to leave the hospital, understands their condition and treatments, and has been referred to outpatient specialists or therapy, as needed. Providing clear instructions and arrangements help ensure that the patient adheres to care, medication, and lifestyle changes outside of the hospital (Bowles et al, 2014, Philips et al, 2004, DeCaporale-Ryan et al, 2017, and Verhaegh et al, 2014). The primary outpatient clinician is responsible for the care of the patient outside of the hospital and can prevent readmissions by ensuring accessibility to care and availability for consultations within 30 days after discharge. Through their individual roles and together through coordinated care, these clinicians can reduce the risk of readmission. NQF panel and committee members have voted on this measure several times, all of which concluded in favor of endorsing the measure. Final endorsement of the measure was deferred to the Spring 2020 Consensus Standards Approval Committee (CSAC) due to efforts to reduce burden for committee members who may need to prioritize COVID-19 in their communities. **Comment:** One commenter stated that HWR measure lacks transparent evaluation on whether it is appropriate to apply the readmission of one patient to multiple physicians since no evidence or testing was provided to support the attribution of this measure to the three distinct groups (discharge physician, primary inpatient care provider, and outpatient primary care provider) during NQF endorsement review. In addition, most of the evidence used to support attribution to physicians involves multiple partners and clinicians such as the health system, hospital, nurse, and/or pharmacist, and there was insufficient evidence provided to support that physicians and practices using the proposed attribution approach. The commenter questioned the ability of the HWR to meaningfully distinguish better or worse performers based on the available benchmarks from the 2017 performance period.

Category	Description
	Commenters noted there is also a need to determine if additional reductions in scores can be made because readmission rates now somewhat stable. The commenter stated that they did not believe that assignment of responsibility of the reduction of readmissions to multiple physicians and practices in MIPS is appropriate. Lastly, the impact that social risk factors in the risk adjustment model on performance rates has not been fully explored. Due to all of these concerns, the commenter stated that physicians should not be held accountable for the HWR measure and the measure should be removed from the program. **Response:** While the existing literature on the association between clinicians and patient outcomes may be sparse, the TEP and clinical consultants, most of whom are clinicians themselves, supported the attribution model and identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions; and therefore, together, can reduce the risk of readmission. Clinicians are critical contributors to quality improvement, whether as change agents and influencers of health systems or key stakeholders whose acceptance is required for successful or long-lasting improvements. The measure is intended to improve upon the current ACR measure within MIPS, which unduly attributes readmissions to the clinician that provide the plurality of care during the measurement period, to more appropriately attribute readmissions to up to three clinician groups with the ability to influence the risk of readmission. The shared attribution is meant to reflect the reality that multiple factors and clinicians contribute to patient care and influence outcomes as well as promote a system change towards coordination of care for the benefit of patients. Implementation and reporting of the measure will provide further data and inform the practicality of the attribution model. As done with all measures publicly reported as part of payment programs, we will monitor use of the measure and test the measure on an annual basis. Using data from July 2015 to June 2016, the median risk-standardized readmission rate was 15.3 percent and range was 7.0 percent to 25.1 percent. In other words, patients can expect to have a readmission within 30 days of discharge on an overage of 15.3 percent of the time. The best performing clinician groups (7.0 percent) are performing 54.2 percent better than an average performer, while the worse performing clinician groups (25.1 percent) are performing 64.1 percent worse than an average performer. This variation in performance indicates a clear quality gap in which some clinician groups are able to achieve substantially lower than average rates, while up to a quarter of patients for other clinician groups are being readmitted, possibly without clinician group awareness. Recent studies examining trends in readmissions following specific conditions and procedures indicate that similar quality measures and policies have effectively decreased readmission rates and remain important metrics (Blecker et al, 2019, Carey et al, 2015, Mellor et al, 2017, Wasfy et al, 2017). The developer conducted social risk factor testing using two variables that are available and reliably measured, including dual-eligible status and Agency for Healthcare Research and Quality (AHRQ) SES index score. For both social risk factors, the correlation between the adjusted and unadjusted scores was 0.99, indicating extremely high agreement. In addition, they also tested the absolute change in risk-adjusted readmission rates. When incorporating the dual eligible risk factor, the largest change in a hospital-level risk-adjusted readmission rate was 1.74 percent for clinician groups. When incorporating low AHRQ SES, the largest change in a hospital-level risk-adjusted readmission rate was 2.45 percent. Both analyses support the notion that adding these social risk factors would have minimal impact on measure scores. Ongoing research aims to identify valid patient-level social risk factors and highlight disparities related to social risk, and as additional variables become available, they will be considered for testing and inclusion within the measure. **Comment**: One commenter opposed this measure, citing broad-based concerns about the 30-day window for readmissions in CMS measures. Those concerns are heightened with the re-specification of the measure to apply to physician groups in the MIPS. There are numerous social, economic and logistical hurdles that can occur during a 30-day readmission window, many of which are independent of a physician's or group's behavior. If the measure window were shortened to 7 days, attribution would improve. **Response:** We thank the commenter for their comment. The measure is a re-specified version of the hospital-level measure, "Hospital-Wide All-Cause, Unplanned Readmission Measure" (NQF #1789), which is currently reported within IQR, and the "All-Cause Readmission" measure, Q458, which has been in the MIPS program since 2017, both of which also use a 30-day outcome timeframe. The 30-day timeframe is consistent with other CMS readmission measures endorsed by NQF and publicly reported. The literature demonstrates that older adults are more vulnerable to adverse health outcomes for 30 days post discharge, readmissions occurring within 30 days of discharge can be influenced by care and early transition to the non-acute care setting, and that the 30-day timeframe is a clinically meaningful period for providers to communicate with each other and their patients to reduce readmissions. Furthermore, during development of the hospital-level HWR measure, the developer reviewed time to readmission curves over time, which illustrated that rapid early accrual of readmissions, followed by a stable readmission rate, eventually stabilizing by 30 days. The 30-day readmission timeframe is based upon numerous studies that have been completed assessing the association between quality of inpatient or transitional care and early readmission rates (typically 30 days). We believe that a 7-day readmission timeframe may not provide a complete representation of post-discharge observation and follow-up periods that may influence readmissions. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years. **Comment:** One commenter stated that comparing to the 30-Day All-Cause Hospital Readmission measure, many exclusions have been dropped from the measure, thereby increasing the denominator. **Response:** We thank the commenter for their comment. The goal is not to compare the data from the All-Cause Hospital Readmission measure to the Hospital-Wide, 30 Day, All-Cause Unplanned Readmission (HWR), but to replace the All-Cause Hospital Readmission measure with a more robust measure as it is based upon the original hospital-level measure has been most rigorously tested and vetted. The measure is intended to improve upon the current ACR measure within MIPS, which unduly attributes readmissions to the clinician that provide the plurality of care during the measurement period, to more appropriately attribute readmissions to up to three clinician groups with the ability to influence the risk of readmission. There are several exclusion criteria applied to the measure population ("starting cohort"), in order to identify the appropriate denominator patient population. Additionally, the measure is risk adjusted to account for differences in patient demographics and clinical characteristics across hospitals. After consideration of public comments, we are finalizing the *Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups* measure as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

A.2. Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

Category	Description
NQF #: / eCQM NQF #:	3493 / N/A
Quality #:	480
Description:	This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is complication defined as acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock complications within seven days from the index admission date; death, surgical site bleeding, and pulmonary embolism within 30 days from the index admission; mechanical complications and periprosthetic joint infection/wound infection within 90 days of the index admission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes".
Denominator:	Patients eligible for inclusion in the measure are those age 65 years and older admitted to non-federal acute care hospitals. An index admission is the hospitalization during which an elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) procedure was performed and to which the complication outcome is attributed. Eligible index admissions are identified using International Classification of Diseases-Tenth Revision-Procedure Coding System (ICD-10-PCS) procedure codes in Medicare inpatient claims data. For risk adjustment and outcome assessment, patients must have continuous enrollment in Medicare fee-for-service (FFS) for 12 months prior to the procedure and 90 days after it. The measure cohort is fully harmonized with the existing hospital-level measure.
Exclusions:	This measure excludes from the denominator admissions for patients: 1. With a femur, hip or pelvic fracture coded in the principal discharge diagnosis field for the index admission. 2. Undergoing partial hip arthroplasty (PHA) procedures (with a concurrent Total Hip Arthroplasty or Total Knee Arthroplasty [THA/TKA]). 3. Undergoing revision procedures (with a concurrent THA/TKA). 4. Undergoing resurfacing procedures (with a concurrent THA/TKA). 5. With a mechanical complication coded in the principal discharge diagnosis field for the index admission. 6. With a malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field for the index admission. 7. With a procedure code for removal of implanted devices/prostheses. After excluding the above admissions to identify elective primary THA/TKA procedures, the measure also excludes admissions for patients: 8. Who were transferred to the index hospital. 9. Who leave the hospital against medical advice (AMA). 10. With more than two THA/TKA procedure codes during the index hospitalization. Note: The measure does not count complications that occur in the outpatient setting and do not require a readmission.
Measure Type:	Outcome
Measure Domain:	Patient Safety (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Measure Implementation:	MIPS eligible clinicians and groups / 25 case minimum / 3 year performance period (October 1st – September 30th)
Rationale:	This risk-standardized complication rate administrative claims measure was proposed to incentivize improved coordination of care, thereby reducing the number of hospitalizations and days hospitalized for patients, reducing rates of complications, and promoting cost savings resulting from fewer hospitalizations. This measure can improve the quality of surgical care delivery and follow-up care for a common and costly surgical procedure performed for Medicare patients. This measure is a re-specified version of an existing, publicly reported hospital measure, NQF #1550, located at https://innovation.cms.gov/files/fact-sheet/bpciadvanced-fs-nqf1550.pdf. Additionally, as an administrative claims measure, there is no separate reporting burden. The measure was evaluated by the MAP and is supported for rulemaking and is NQF endorsed (NQF #3493). The measure steward indicated variability among providers and groups with the risk standardized complication rates (RSCR) ranging from 1.2 percent to 7.2 percent across the groups. In adapting the measure for MIPS eligible clinicians, it will assess the same cohort of patients as the hospital measure, but attribute complications to a larger number of entities with a typically lower volume. Thus, we anticipate that the MIPS THA/TKA complication measure will reflect meaningful variation across MIPS eligible clinicians. The median RSCR for MIPS eligible clinicians with more than 25 cases was 2.7 percent with a minimum interquartile range (IQR) of 2.4 percent - 3.2 percent. The median RSCR for MIPS eligible clinician groups with more than 25 cases was 2.8 percent, with a minimum IQR of 2.4 percent - 3.1 percent. This indicates that 50 percent of clinicians have a complication rate of 2.7 percent or more after adjusting for patient age and comorbidities. The best performing clinicians (1.2 percent) are performing 55.6 percent better than an average performer, while the worst performing clinicians (7.2 percent) are performing 166.7 percent worse than an average performer. The best performing clinician groups (1.4 percent) are performing 50 percent better than an average performer, while the worst performing clinicians (5.7 percent) are performing 103.6 percent worse than an average performer. The measure steward believes these results support meaningful variation in rates across clinician and clinician groups with room for improvement. This measure is a re-specification of the existing, publicly reported hospital-level total hip/knee arthroplasty (THA/TKA) 90-day complication measure and has been designed to align with the cohort and methods of that measure. This measure uses 36 months of administrative claims data to calculate risk-standardized complication rates (RSCRs) for MIPS eligible clinicians and MIPS eligible clinician groups with 25 or more cases within the 3-year performance period. This approach balances measure reliability with maximizing the number of clinicians or clinician groups measured. For 2023 payment determination, the performance period will include administrative claims from October 1, 2018 to September 30, 2021. The measure's numerator assesses the occurrence of complications in the 90 days following the index admission date; therefore, ending the 3-year performance period on September 30th of the calendar year will allow time for numerator assessment. Based on the information provided by the measures steward, we believe this measure is evidence-based and represents an important clinical outcome. For further information regarding the implementation of this measure, please see IV.A.3.c.(1)(e)(i) of this final rule. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

Category	Description

Comment: One commenter supported this new measure, citing that that there is no data submission requirement from clinicians. The commenter requested that consideration be given to fast-tracking this measure for reporting on Physician Compare, as a complement to measure already available on Hospital Compare, so that beneficiaries potentially could access information about the quality and clinical outcomes of joint replacement surgeons. A second commenter stated that orthopedic surgeons would choose to report this measure and also asked for the measure to be included on Physician Compare, or other CMS site.

Response: We thank the commenter for supporting this new measure for inclusion in the MIPS program.

Comment: One commenter indicated that it has urged CMS to consider measure reliability on a measure-by-measure basis and applauds CMS for incorporating a 3-year window to increase the integrity of this measure. The commenter has expressed concerns to CMS about the difficulty of calculating a high level of reliability and validity with 12 months of data for an individual clinician, and has urged CMS to measure surgical care at the group or facility level in order to increase statistical power. This is especially important for procedures with a low complication rate. The commenter supported the direction of this measure since it evaluates individuals and groups over a longer time period for increased reliability, and also aligns with the hospital measure. The commenter recommended that CMS allow for a longer look back period for other MIPS measures, where appropriate. Although risk-adjusted clinical data from a high-fidelity registry is often preferred to claims data, a 36-month collection period of claims data can be used as a proxy for quality outcomes with low event rates.

Response: We thank the commenter for supporting this new measure for inclusion in the MIPS program.

Comment: Several commenters opposed the addition of this measure for the 2021 performance year. Clinicians and group practices need stability now more than ever, and this is not the time to add new metrics, particularly to a category that groups are familiar with already. The commenter expressed significant concerns around administrative claims measures. While CMS asserts these measures do not increase reporting burden since they are calculated on clinicians' behalf, it takes time to study the measures themselves, understand how clinicians are evaluated, and determine how (or if) clinicians can influence performance. With registry or EHR reporting, clinicians can receive real time feedback on measure performance and evaluate whether changes are needed to facilitate improvement. Claims-based measures do not offer the same opportunity, which makes it difficult to improve performance or drive meaningful change. Another commenter said this measure should be delayed and implemented as part of an Orthopedic MVP instead of being implemented as a category-wide population health measure.

Response: We believe that it is important to capture patient outcomes, that is, complication rates, for these procedures to allow for a more comprehensive view of quality of care, patient safety, prevention of and response to complications, and coordination of care. We believe this measure has the potential to illustrate variations seen in quality, help to inform patient choice, be a driver of quality improvement while enhancing care coordination. While we can appreciate the desire for stability, we believe the addition of an Administrative Claims based measure has low burden on clinicians, covers a gap within MIPS, and is important in driving quality care. Real-time feedback is not a guaranteed aspect of the eCQMs Specifications or the MIPS CQMs Specifications collection type, but may be a service provided, for example, by a vendor. While the administrative claims does not provide real-time feedback, CMS supplies eligible clinicians and eligible clinician groups with confidential reports that provide information on measure performance, including patient-level data, to help drive quality improvement. In addition, since they utilize claims data submitted for payment purposes, they provide data elements that are validated through CMS monitoring and auditing processes and introduce no burden collection of vital information related to decreasing complications from elective primary THA and/or TKA therefore improving patient outcomes.

Comment: One commenter did not support including this new measure and requested that if CMS finalizes the measure, it must delay implementation of the measure, not include 2020 data, and provide advance notice given the measure utilizes retrospective data. The commenter was concerned that there is insufficient evidence on how an individual physician or practice could reduce complication rates in these patients and the scientific acceptability of this measure is questionable. In addition, the reliability scores when applying this measure to eligible clinicians with more than 25 admissions was below the minimum acceptable threshold. The commenter was also concerned about the impact COVID-19 may have on volume and outcomes, and did not believe any physician should be evaluated on outcomes that includes 2020 data. Finally, information on how the measure would perform using the MIPS benchmark methodology and Physician Compare Star Ratings has not been provided. In addition, two commenters opposed having a 3-year performance period for this measure. The commenter thought that it would be operationally difficult and would delay actionable feedback and payment adjustments for years. The data received and scored across two years would not reflect true performance during the performance year and would impact scoring on an episode that they treat fewer than 25 times per year. Two commenters thought that a 3-year performance period is far too long to provide meaningful, timely data that would help to inform quality improvement activities and convert it to a data reporting exercise.

Response: THA/TKA elective procedures dramatically improve quality of life and function but can result in serious complications. The associated risk and performance of surgeons are important factors for patients to consider when deciding whether to undergo the elective operation. Current clinician-level THA/TKA quality improvement measures are generally limited to evidence-based processes of care. Measurement of patient outcomes, such as complications, allows for a more comprehensive view of quality of care, capturing complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment.

During the NQF initial endorsement review process, the measure specifications and testing was reviewed by a scientific methods panel, which concluded that the measure was scientifically acceptable, contributing to the ultimate endorsement of the measure. Measure reliability testing conducted by the developer consisted of two approaches, one of which demonstrated acceptable reliability with mean signal to noise reliability scores of 0.786 and 0.769 for eligible clinicians and eligible clinician groups, respectively (Adams et al, 2010). While the other approach, test-retest reliability, yielded lower but still fair reliability scores of 0.35 and 0.47 for eligible clinicians and eligible clinician groups, respectively, the reliability results are consistent with MIPS requirements (Landis and Koch, 1977). During TEP meetings and the NQF initial endorsement review process, stakeholders argued that eligible clinicians and eligible clinician groups with less than 25 cases should also be measured since those surgeons perform fewer procedures and may benefit from quality measurement. A minimum case count of 25 ensures that a measure result is available for most eligible clinicians and eligible clinician groups while maintaining measure reliability. This ensures that we are capturing a more complete patient population by including a broadened performance period. With regard to the 3-year performance period, specifically the COVID-19 Public Health Emergency (PHE) impact, this approach supports clinicians or clinicians groups by assuring an adequately sized cohort of THA/TKA elective procedures for the assessment of complications post procedure. An adequate cohort is necessary to demonstrate reliability of results. We expect a decline in elective procedures during the PHE; however, the threshold will protect those clinicians or clinician groups that did not meet the 25 case requirement to ensure reliability. This reporting period approach balances measure reliability with maximizing the number of clinicians or clinician groups measured and quantifies the outcome derived from the data. For 2023 payment determination, the performance period will include administrative claims from October 1, 2018 to September 30, 2021. Though the performance period will span three years, performance data will be provided each year to reflect the corresponding performance period. This will ensure meaningful and timely data is available.

Comment: One commenter stated it would be beneficial to understand why the claims-based measures differ between the two programs as the ACO has a Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions measure rather than the Risk-Standardized measure proposed here. The commenter asked that measures be aligned between programs where it makes sense to do so.

Response: We thank the commenter for their comment. The "Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions" measure was specifically developed to fulfill a measurement gap, as identified by NQF, for the ambulatory setting, which the literature demonstrates may lower readmissions for

Category	Description
	patients with multiple chronic conditions through improving access to care, supporting self-care at home, coordinating care across providers, and integrating social work, nursing, and medical services. We previously proposed but did not finalize the All-Cause Unplanned Admissions for Multiple Chronic Conditions measure for the 2021 MIPS performance period/2023 MIPS payment year to allow more time for considering feedback from the MAP on the measure (84 FR 62956). We endeavor to align with other reporting programs when able and will consider inclusion of All-Cause Unplanned Admissions for Multiple Chronic Conditions for future program years through future rulemaking. After consideration of public comments, we are finalizing the *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)* measure as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

TABLE Group B: New Specialty Measures Sets and Modifications to Previously Finalized Specialty Measure Sets Finalized for the 2023 MIPS Payment Year and Future Years

We proposed to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, proposed the addition of new measures for inclusion in MIPS, and considered the feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remained static, but the individual measures had proposed substantive changes in Table Group D. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent fully the regulatory definition of high priority measures. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table B as follows: NQF # / eCQM NQF #.

NOTE:

- In the instance a title and/or measure description had a substantive change finalized in Table Group D, the revised title and/or measure description is reflected in the specialty measure sets located in Table Group B.
- Under Table Group B, we respond to comments that are related to new measures that were proposed for addition to measure sets, and measures that were proposed for removal. Any comments received on previously finalized measures are out of scope and not included in this final rule.
- Measures that were not finalized for removal in this final rule have been added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for their retention is addressed under Table Group C.

The definition of high priority at § 414.1305 includes an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

The following specialty measure set was excluded from this group because we did not propose any changes to this specialty measure set: Anesthesiology. Therefore, we refer readers to the CY 2020 Quality Payment Program final rule for the previously finalized Anesthesiology specialty measure set (84 FR 63218 through 63219).

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES FINALIZED FOR ADDITION TO THE ALLERGY/IMMUNOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage sinusitis. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage sinusitis. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage asthma. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.

B.1. Allergy/Immunology

MEASURES FINALIZED FOR ADDITION TO THE ALLERGY/IMMUNOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma**: The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/Immunologists treat and frequently manage asthma. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.
Comment: One commenter thanked CMS for the addition of measures Q331, Q332, Q398, and Q444 to the Allergy/Immunology set that it had requested in prior years comments. **Response:** We thank the commenter for supporting the addition of the four measures to this specialty set. After consideration of public comments, we are finalizing the measures for addition to the *Allergy/Immunology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.2. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.2. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ *	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.2. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.3a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation
§ ! (Efficiency)	N/A / N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology Foundation
! (Efficiency)	N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And □ Most recent tobacco status is Tobacco Free -- And □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And □ Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.3a. Cardiology

MEASURES FINALIZED FOR ADDITION TO THE CARDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We proposed to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Cardiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.3b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.3b. Electrophysiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ELECTROPHYSIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	348	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.	American College of Cardiology Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Electrophysiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.4. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.5. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419 e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418 e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028 e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872 e	281	CMS149v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association / American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association /American Academy of Neurology
* ! (Outcome)	0710 / 0710e	370	CMS159 v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Patient Safety)	N/A / 1365e	382	CMS177 v9	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.5. Clinical Social Work

MEASURES FINALIZED FOR ADDITION TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	We proposed in Table D.9 to expand the measure's applicability to include coding that would include clinical social worker clinician type. With the expanded patient population and the clinically relevance to this clinician type, we proposed to add to the Clinical Social Work specialty set.

Comment: One commenter stated that in the palliative care setting, clinical social workers are trained to provide counseling services and play an important role in goals of care discussions, naming a surrogate decision maker and developing an advance care plan. The commenter's members regularly hold these discussions with patients and families during the course of care. As this measure is added to the Clinical Social Work set, the commenter strongly recommended that clinical social workers be added to the list of providers who can use CPT code 99497 and the add-on code 99498 and bill for advance care planning services. A second commenter supported the addition of measure Q047 to the Clinical Social Work set.

Response: We thank the commenters for their support of the addition of clinical social worker clinician type. In regards to the comment requesting updates to CPT codes 99497 and 99498, these codes are not necessary for the utilization of measure Q047, as they are included within the measure to show examples as to what services would typically satisfy the quality action. As noted in the measure specification, the quality-data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data and submit data to CMS on the clinicians behalf. However, for Medicare Part B claims, adding these codes to the numerator could potentially skew performance calculations and not allow proper distribution of numerator outcomes that reflect accurate performance.

After consideration of public comments, we are finalizing the measures for addition to the *Clinical Social Work Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.6. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.6. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v9	eCQM Specifications	Outcome	Community/ Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v10	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.7. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.7. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology

B.7. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician- or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.8. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.8. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
* ! (Care Coordination)	N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
*	0507 / N/A	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology
! (Care Coordination)	0509 / N/A	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
* ! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.8. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.8. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0508 / N/A	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms:** Percentage of final reports for screening mammograms that are classified as "probably benign".	American College of Radiology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Diagnostic Radiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.9. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.9. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161 v9	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
	N/A / N/A	254	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.9. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* ! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A / N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.9. Emergency Medicine

MEASURES NOT FINALIZED FOR ADDITION TO THE EMERGENCY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0053 / N/A	418	N/A	Medicare Part B Claims Specifications, MIPS CQM Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture**: The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance	We proposed in Table D.89 to expand the clinical setting to include Emergency Medicine. With the expanded patient population and the clinically relevance to this clinician type, we proposed to add to the Emergency Medicine specialty set.

Comment: One commenter opposed the addition of measure Q418 to the emergency department as an appropriate setting for this measure, stating that emergency department physicians do not manage these types of services. Furthermore, bone density tests often require a prior authorization, which would make this measure infeasible for an emergency medicine physician who does not oversee the ongoing care of a patient outside of the emergency department. A second commenter was also in opposition, stating that osteoporosis management is a chronic condition measure that requires longitudinal care and retrospective data. It is not an accurate reflection of emergency care and should not be attributable to the emergency physician, who only provides acute care management.

Response: We agree that this measure may not fit into the emergency department workflow and that these quality actions may not be feasible for the emergency medicine clinician. We will not finalize the addition of measure Q418 to the Emergency Medicine set.

After consideration of public comments, we are not finalizing measure Q418 for addition to the *Emergency Medicine Specialty Measure Set* as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.9. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE EMERGENCY MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQM Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Emergency Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.10. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS645 v4	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.10. Endocrinology

MEASURES FINALIZED FOR ADDITION TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Endocrinology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.11. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128 v9	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161 v9	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v1 0	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communicati on and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Opioid)	N/A / N/A	305	CMS137 v9	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124 v9	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
	N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
! (Outcome)	0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* ! (Outcome)	0710 / 0710e	370	CMS159 v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v 9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* §	1407 / N/A	394	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: ☐ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND ☐ Most recent tobacco status is Tobacco Free -- AND ☐ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND ☐ Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249 v3	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349 v3	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.11. Family Medicine

MEASURES NOT FINALIZED FOR ADDITION TO THE FAMILY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	We proposed to add this measure to the Family Medicine specialty set. Stakeholders commented, as we agreed, that the Family Medicine set includes several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Family Medicine specialty set.

Comment: Two commenters opposed the addition of measure Q391 to the Family Medicine set, and noted that the measure specifications require a visit with a mental health professional to satisfy the measure (i.e., a visit with a family physician does not satisfy the measure); therefore application to family medicine is inappropriate.

Response: We thank the commenters for their comments. We believe that measure Q391 supports the facilitation of follow up care for patients that have been hospitalized with mental illness and represents a meaningful measure within MIPS. However, we understand the concern provided by the commenters and recognize that the quality action of the measure indicates the follow up is with a mental health practitioner. Therefore, we agree that this measure should not be added to the Family Medicine set.

After consideration of public comments, we are not finalizing measure Q391 for addition to the *Family Medicine Specialty Measure Set* as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE FAMILY MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Family Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.12. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenter ological Association
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Po pulation Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GASTROENTEROLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroenterological Association	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Gastroenterology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.13 General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.13. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.13. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.13. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

Comment: One commenter indicated that measures Q047, Q128, Q130, Q226, Q317, and Q374, included in the General Surgery set, have substantive changes proposed under the applicable D Tables (D.9, D.24, D.25, D.46, D.64, and D.73) that measure preventive care services, which do not directly align with most surgical workflows. The commenter believes that administering and measuring population health and preventive care activities are important, but these measures should not make up the majority of the General Surgery set as they offer little support in understanding the quality of surgical care.

Response: We did not propose any changes to the General Surgery set. Of note, the substantive changes finalized for the aforementioned measures do not change the intent of the measures. We encourage the commenter to submit this comment during the Solicitation for Specialty Sets for potential implementation in future years.

B.14. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0710 / 0710e	370	CMS159v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* § ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
* ! (Outcome)	N/A / N/A	476	CMS159v9	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GERIATRICS SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GERIATRICS SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
Comment: One commenter supported the removal of measures Q412 and Q414 from the Geriatrics set. **Response:** We thank the commenter for supporting the removal of these measures. After consideration of public comments, we are finalizing the measures for removal from the *Geriatrics Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program. Also note that measure Q408: Opioid Therapy Follow-up Evaluation should have been included in the removal table for the Geriatrics set in the 2021 PFS proposed rule as it is being removed from the MIPS program.								

B.15. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.15. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.16. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.16. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
§	N/A / N/A	475	CMS349 v3	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.17. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v9	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0418 / 0418e	134	CMS2v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Opioid)	N/A / N/A	305	CMS137v9	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. □ Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. □ Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v9	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years •	National Committee for Quality Assurance

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery Foundation

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
! (Outcome)	0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* ! (Outcome)	0710 / 0710e	370	CMS159v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND Most recent tobacco status is Tobacco Free -- AND Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249v3	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v3	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.17. Internal Medicine

MEASURES FINALIZED FOR ADDITION TO THE INTERNAL MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / 0104e	107	CMS161 v9	eCQM Measure Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica	We proposed to add this measure to the Internal Medicine specialty set. Stakeholders commented, and we agreed, that the Internal Medicine set include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Internal Medicine specialty set.
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	We proposed to add this measure to the Internal Medicine specialty set. Stakeholders commented, and we agreed, that the Family Medicine set include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Internal Medicine specialty set.
We received no comments on the measures for proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Internal Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERNAL MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Internal Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.18. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.18. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	MIPS CQMs Specifications, eCQM Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.18. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERVENTIONAL RADIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	437	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure:** Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.	Society of Interventional Radiology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Interventional Radiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.19. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Mental/Behavioral Health specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128 v9	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
*	N/A/ / 0104e	107	CMS161 v9	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/P opulation Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v1 0	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149 v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	366	CMS136 v10	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* ! (Outcome)	0710 / 0710e	370	CMS159 v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / 1365e	382	CMS177 v9	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: ● The percentage of discharges for which the patient received follow-up within 30 days after discharge. ● The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.20. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.20. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.20. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association

B.21. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
*	N/A / 2872e	281	CMS149 v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months.	American Academy of Neurology
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.21. Neurology

MEASURES FINALIZED FOR ADDITION TO THE NEUROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine	We proposed to include this measure in the Neurology specialty set based upon stakeholder feedback, as it is clinically relevant to this clinician type.
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine	We proposed to include this measure in the Neurology specialty set based upon stakeholder feedback, as it is clinically relevant to this clinician type.

Comment: One commenter supported the addition of measures Q277 and Q279 to the Neurology set.

Response: We thank the commenter for supporting the addition of these measures to the Neurology set.

After consideration of public comments, we are finalizing the measures for addition to the *Neurology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROLOGY SET Note: In this final, we proposed the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

Comment: One commenter supported the removal of the three retired opioid measures, Q408, Q412, and Q414 from the Neurology set.

Response: We thank the commenter for supporting the removal of measures Q408, Q412, and Q414 from the Neurology set, as they are being removed from the MIPS program.

After consideration of public comments, we are finalizing the measures for removal from the *Neurology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.22. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.22. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications fo a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated i all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis t be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.22. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement

B.22. Neurosurgical

MEASURES FINALIZED FOR ADDITION TO THE NEUROSURGICAL SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	We proposed to include this measure in the Neurosurgical specialty set as we received previous stakeholder feedback to include this measure within the specialty set. We agreed with that stakeholder that it is clinically relevant to this clinician type.
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	We proposed to include this measure in the Neurosurgical specialty set as we received previous stakeholder feedback to include this measure within the specialty set. We agreed with that stakeholder that it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Neurosurgical Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.23. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.23. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS155v9	eCQM Specifications	Process	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. Percentage of patients with counseling for nutrition. Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	.	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
* §	N/A / N/A	309	CMS124v9	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v9	eCQM Specifications	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication.	Centers for Medicare & Medicaid Services

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
! (Patient Safety)	N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249v3	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v3	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.25a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	067	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Society of Hematology
	N/A / N/A	070	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry**: Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	American Society of Hematology
§ ! (Appropriate Use)	0389 / 0389e	102	CMS129 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
*	0041 / 0041e	.	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* ! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology
* §	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
* § ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
* § ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS645 v4	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	069	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.	American Society of Hematology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Oncology/Hematology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.25b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.25b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0389 / 0389e	102	CMS129 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* ! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology

B.26. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.26. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0086 / 0086e	012	CMS143v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Academy of Ophthalmology
*	0087 / N/A	014	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS142v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v9	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology

B.26. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.26. Ophthalmology

MEASURES FINALIZED FOR ADDITION TO THE OPHTHALMOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance	We proposed in Table D.48 to expand the measure's applicability to include the ophthalmology patient population. With the expanded patient population and the clinical relevance to this clinician type, we proposed to add to the Ophthalmology specialty set.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Ophthalmology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.27. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v 10	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communicat ion and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communicat ion and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	375	CMS66 v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	376	CMS56 v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.		This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Orthopedic Surgery Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.28. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications. CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE OTOLARYNGOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Otolaryngology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.29. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.29. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	1854 / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.30. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS155v9	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. □ Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. □ Percentage of patients with counseling for nutrition. □ Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS117v9	eCQM Specifications	Process	Community / Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	305	CMS137v9	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. □ Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. □ Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v9	eCQM Specifications	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	366	CMS136v10	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* ! (Outcome)	0710 / 0710e	370	CMS159v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	N/A / N/A	379	CMS74v10	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / 1365e	382	CMS177v9	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication/Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
* §	1407 / N/A	394	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.30. Pediatrics

MEASURES FINALIZED FOR ADDITION TO THE PEDIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance	We proposed in Table D.18 to expand the measure's applicability to include the pediatric patient population. With the expanded patient population and the clinical relevance to this clinician type, we proposed to add to the Pediatric specialty set.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Pediatrics Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.31. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.31. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419 e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.31. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028 e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.31. Physical Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PHYSICAL MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.		This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Physical Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.32. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
*	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient	N/A / N/A	181	N/A	Medicare Part B Claims Measure	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older	Centers for Medicare & Medicaid

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Safety)				Specifications, MIPS CQMs Specifications			with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients	Focus on Therapeutic Outcomes, Inc.

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / 2872e	281	CMS149 v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	eCQM Specifications. CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.32. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

Comment: Once commenter was supportive of adding measures Q283 and Q286 to the Physical Therapy/Occupational Therapy set.

Response: We thank the commenter for supporting the addition of measures Q283 and Q286 to this specialty set.

After consideration of public comments, we are finalizing the measures for addition to the *Physical Therapy/Occupational Therapy Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology	We proposed to remove this measure from the Physical Therapy/Occupational Therapy set as it is duplicative of measure Q182: Functional Outcome Assessment. Measure Q182 includes much of the patient population in measure Q282, but is more robust in that is requires more frequent assessments and a plan of care.
Comment: One commenter supported the removal of measure Q282 from the Physical Therapy/Occupational Therapy set and agreed with the rationale that the measure is duplicative to measure Q182. **Response:** We thank the commenter for supporting the removal of measure Q282 from this specialty set. After consideration of public comments, we are finalizing the measures for removal from the *Physical Therapy/Occupational Therapy Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.33. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.33. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.33. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.34. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.34. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.34. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.35. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349 v3	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.36. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.36. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.36. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance

B.36. Pulmonology

MEASURES FINALIZED FOR ADDITION TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Pulmonology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.37. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.37. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services

B.37. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* §	0028 / 0028e	226	CMS138 v9	Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v9	Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.37. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.38. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.38. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	.	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.38. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.38. Skilled Nursing Facility

MEASURES FOR ADDITION TO THE SKILLED NURSING FACILITY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance	We proposed in Table D.48 to expand the measure's applicability to include the skilled nursing facility patient population. With the expanded patient population and the clinical relevance to this clinician type, we proposed to add to the Skilled Nursing Facility specialty set.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Skilled Nursing Facility Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.39. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.39. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Speech Language Pathology

MEASURES FINALIZED FOR ADDITION TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services	We proposed to add this measure to the Speech Language Pathology specialty set as the specific codes were finalized for inclusion in 2020 performance period. We proposed to include this measure in the Speech Language Pathology specialty set as it is clinically relevant to this clinician type.
We received no comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Speech Language Pathology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.40. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.40. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons

B.40. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user .	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.40. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.40. Thoracic Surgery

MEASURES FINALIZED FOR ADDITION TO THE THORACIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	0236 / N/A	044	N/A	MIPS CQM Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery**: Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services	We proposed to add this measure to the Thoracic Surgery set as it is clinically relevant to this clinician type. This set includes additional CABG quality measures and inclusion of this measure would allow for a complete assessment of quality for this surgical procedure.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Thoracic Surgery Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.41. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.41. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.41. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.41. Urgent Care

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE URGENT CARE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Urgent Care Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.42. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0389 / 0389e	102	CMS129 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
	0390 / N/A	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
*	N/A / N/A	462	CMS645v4	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	476	CMS771 v2	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUS) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.43. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.43. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.43. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons

B.43. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND □ Most recent tobacco status is Tobacco Free -- AND □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND □ Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)

TABLE Group C: Previously Finalized Quality Measures Finalized for Removal in the 2023 MIPS Payment Year and Future Years

In this final rule, we are removing 11 previously finalized quality measures from the MIPS Program for the 2021 MIPS performance period/2023 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 PFS final rule (83 FR 59763 through 59765).

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), additional criteria that we use for the removal of measures also includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent. Beginning with the 2020 MIPS performance period/2022 MIPS payment year, we also refer readers to the CY 2020 PFS final rule (84 FR 62957 through 62959) for additional quality measure removal criteria.

NOTE: Since publication of the measures in Table C in CY 2021 PFS proposed rule, we have determined the following measures will be retained in the 2021 MIPS performance period/2023 MIPS payment year: Q024, Q048 (MIPS CQMs Specifications collection type only), and Q337. As such, these measures have been removed from Table C and integrated back into the relevant previously finalized measure sets under Table B in this final rule. Our decisions not to finalize these measures for removal in this final rule are detailed in our responses to the public comments for these measures in Table Group C.

TABLE Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal in the 2023 MIPS Payment Year and Future Years

C.1. Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	024
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure supports communication between the physician treating the fracture and the clinician managing the patient's on-going care, but does not ensure that the patient receives the appropriate treatment or testing for osteoporosis. We believe measure Q418: Osteoporosis Management in Women Who Had a Fracture represents a more robust quality outcome in the management of patients with osteoporosis who experience a fracture since the clinical focus of this measure is the care of the patient rather than just the communication of the care plan for on-going post fracture care.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed the removal of measure Q024, stating that it does not believe this measure is duplicative of measure Q418 as that measure only focuses on women, and not the entire population of possible concern. While the commenter appreciated the measure is a process measure that does not address appropriate treatment or testing, this measure captures an important aspect of care continuity for a large proportion of Medicare beneficiaries with fractures that is not addressed in any other MIPS quality measures.

Response: We agree that treatment of osteoporosis is important, however, measure Q024 does not ensure treatment of the patient only that the fracture was communicated to the clinician managing the patient's on-going care. Measure Q418 is more robust in that it requires a bone mineral density test or pharmacologic therapy. After careful consideration, we will maintain this measure for consistency and stability as it is not topped out and still in alignment with guidelines, but may consider removal in the future.

After consideration of public comments, we are not finalizing the removal of measure Q024 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.2.Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	048
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measures initiative. This is a process measure that only requires an assessment for the presence or absence of urinary incontinence, which by itself may not have a meaningful direct impact on patient care as the screening itself does not indicate a plan of care was implemented. Additionally, the Medicare Part B Claims Measure Specifications collection type has reached the end of the topped out lifecycle (82 53640).
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed removal of measure Q048, stating that according to the Women's Preventive Services Initiative, screening for urinary incontinence is important as this condition is underdiagnosed and undertreated in the United States. This practice screens for urinary incontinence in order to provide the appropriate diagnosis and ultimately the plan of care, and screens all women over 65 as it is clinically relevant for its practice.

Response: While we agree that this is an important concept, the measure for assessment alone is low-bar and may not drive quality outcomes meaning completion of a screening does not indicate appropriate treatment was provided to the patient. We believe that measure Q050 allows clinicians to support patients screened positive for urinary incontinence and support the needs of these patients with quality being captured upon providing the patient with a plan of care. After careful consideration, we will maintain the MIPS CQMs Specifications collection type for consistency and stability as it is not topped out and still in alignment with guidelines, but may consider removal in the future. The Medicare Part B Claims Measure Specifications collection type has reached the end of the topped out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

Comment: Two commenters opposed removal of measure Q048 from the MIPS program and therefore the Obstetrics/Gynecology and Geriatrics specialty sets because evaluation of incontinence is an important initial evaluative process for female patients 65 or older. While sensible to remove the measure due to the topped out status, it seems reasonable to consider modification to transition this measure to an outcomes measure. The commenter received requests to delay removing this measure until MVPs are implemented and because many TINs using this measure are short of their required six measures for MIPS reporting.

Response: Measure Q048 does not require a quality action (follow up, plan of care, etc.) that links to improved outcomes. The measure does not assess a clinical outcome nor one of the defined MIPS high priority areas. Measure Q050 is a more robust measure that requires a quality action (plan of care) for the appropriate patient population screened and diagnosed with urinary incontinence. We would encourage the commenter to collaborate with the measure to expand the population of Q050 to include all women to be screened for urinary incontinence and if positive, develop a plan of care to create a single comprehensive quality measure. After careful consideration, we will maintain the MIPS CQMs Specifications collection type for consistency and stability as it is not topped out and still in alignment with guidelines, but may consider removal in the future. The Medicare Part B Claims Measure Specifications collection type has reached the end of the topped out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the removal of measure Q048 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years for the Medicare Part B Claims Specifications collection type only (see Table D.113). Measure Q048 will remain in the MIPS program for 2021 for the MIPS CQMs Specifications collection type.

C.3. Hematology: Multiple Myeloma: Treatment with Bisphosphonates

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	069
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.
Measure Steward:	American Society of Hematology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure does not align with current treatment guidelines and could inadvertently penalize eligible clinicians who are treating patients appropriately (i.e., Prolia), by excluding those patients instead of being numerator compliant. As currently constructed, the measure may produce misleading results.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.
Comment: One commenter was supportive of removing measure Q069 from the MIPS program. **Response:** We thank the commenter for supporting the removal of this measure. After consideration of public comments, we are finalizing the removal of measure Q069 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

C.4. Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

Category	Description
NQF # / eCQM NQF #:	0508 / N/A
Quality #:	146
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for screening mammograms that are classified as "probably benign".
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.428 percent for the MIPS CQMs Specifications collection type and 0.253 percent for the Medicare Part B Claims Measure Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs Specifications collection type and the Medicare Part B Claims Measure Specifications collection type are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter did not support the removal of measure Q146 since reporting difficulties created by the COVID-19 pandemic may limit relevancy of some measures due to reduced services provided. The use of performance period benchmarks for the 2021 performance year introduces uncertainty in measure selection. The removal of this measure would also limit the pool of measures available for breast imagers, and many groups carve out mammography services into separate TINs, thus group reporting does not broaden the list of available measures for these specialists. In addition, the measure could be useful as part of a measure set for a breast imaging MVP. A second commenter urged CMS to temporarily halt the removal of topped out measures for the 2021 performance year to provide clinicians with consistency as they recover from the COVID-19 PHE, particularly those that may be aligned with future MVPs. A third commenter said removal of this measure would limit the number of measures for radiologists and wanted this topped out measure to remain. A fourth commenter acknowledged the topped out data but suggested retaining the measure with an increase in the data completeness threshold to 90-95 percent since there have been no new radiology measures since 2017. A fifth commenter recommended maintaining the existing MIPS quality measures to ensure consistency, reduce a burden, and allow options in the future for MVPs.

Response: While we acknowledge the hardships faced due to the COVID-19 PHE and the specializations found within diagnostic radiation, the performance for measure Q146 has an extremely high and unvarying performance rate. This does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File. The policy for data completeness is established for all measures and is not varied between measures. We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high-priority measures for submission to the Call for Measures for possible future implementation. We understand that ensuring there are measure available for future use in MVPs is important, however, we strive to ensure that all measures align with the Meaningful Measures Initiative, including removal of measures that are extremely topped out.

After consideration of public comments, we are finalizing the removal of measure Q146 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.5. Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	333
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle and has a high performance rate of 2.834 percent for the MIPS CQMs Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	We proposed to update the denominator eligible encounters to include telehealth encounters as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter opposed removal of measure Q333, stating that while performance on this measure has historically been high, it is still possible to further improve clinical outcomes. Patients who undergo CT scans are exposed to radiation, which is correlated with an increased risk of cancer. This measure disincentivizes CT scans when diagnosing uncomplicated cases of adult sinusitis, which leads to better clinical outcomes. Removing this measure also reduces wasteful spending incurred by ordering CT scans.

A second commenter stated that the removal of measure Q333 would impact the Emergency Medicine and Urgent Care sets. The commenter recognizes that it is not necessarily productive to keep measures that have demonstrated consistently high performance over time. At the same time, measure removal policies limiting the number of measures available to emergency medicine impact the ability of emergency medicine physicians to participate in the MIPS program. The commenter indicated that CMS must adopt a process that allows specialties to more rapidly test and replace obsolete measures. CMS should also work with clinical experts to consider ways to encourage the long-term tracking of topped out measures and allow for the reintroduction of previously topped out measures if a performance gap is later identified.

A third commenter urged CMS to temporarily halt the removal of topped out measures for the 2021 performance year to provide clinicians with consistency as they recover from the COVID-19 PHE, particularly those that may be aligned with future MVPs. A fourth commenter recommended maintaining the existing MIPS quality measures to ensure consistency, reduce a burden, and allow options in the future for MVPs. A fifth commenter requested that CMS consider extending the life of this measure with an updated denominator that adds telehealth as an eligible encounter, and the commenter also thought this would be an excellent measure to include in a future MVP.

Response: We agree that this is an important concept and we can appreciate the difficulties of the COVID-19 PHE. We understand that ensuring there are measures available for future use in MVPs is important, however, we strive to ensure that all measures align with the Meaningful Measures Initiative, including the removal of measures that are at the end of the topped out lifecycle. Additionally, by removing measures at the end of the topped out lifecycle, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File. The policy for data completeness is established for all measures and is not varied between measures. We appreciate the comment regarding inclusion of telehealth as an eligible encounter of the measure and encourage the commenter to communicate their request to the measure steward for consideration in future years.

We ensure there is an annual review of quality measures with measure stewards to ensure we maintain measures that reflect meaningful measurement. We believe that measures that are submitted to Call for Measures, vetted by CMS, and reviewed by Measure Applicability Partnership ensure that included MIPS measures are robust and fulfill our goal of incorporating meaningful measurement.

After consideration of public comments, we are finalizing the removal of measure Q333 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.6. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative to measure Q176: Rheumatoid Arthritis (RA): Tuberculosis Screening because we are proposing in Table D.33 substantive changes to measure Q176 that would broaden the denominator by removing the disease specificity criteria. Therefore, the patient population will overlap between these measures; however, measure Q176 has a broader eligible patient population. In the event the proposed substantive change to measure Q176 was not finalized, we considered maintaining this measure to ensure this patient population is being assessed for appropriate tuberculosis screening.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One specialty dermatology practice said it does not have a broad selection of measures to choose from and opposed the removal of measure Q337, stating that the measure is not duplicative to measure Q176. The practice does not diagnosis rheumatoid arthritis, and there is no mention of psoriasis in measure Q176. The commenter suggested that psoriasis be added to measure Q176, or as an alternative, that measure Q176 be eliminated instead since rheumatoid arthritis is mentioned in measure Q337.

A second commenter opposed the removal of measure Q337, citing that the rationale for removal is the proposed substantive changes under Table D.33 to measure Q176, where the measure population would then overlap with measure Q337. However, if changes to measure Q176 are not finalized, measure Q337 would be retained. The commenter stated that the revision to measure Q176 does not sufficiently cover the patients that dermatologist treat or the medications that are used, as are currently reported under measure Q337. See comments under Table D.33 for further recommendations from this commenter.

Response: We proposed a substantive change to measure Q176 in Table D.33 to broaden the denominator by removing the disease specificity criteria. The denominator will now include all patients aged 18 years and older receiving their first course of therapy using a biologic DMARD, regardless of diagnosis. We encourage the commenter to reach out to the measure stewards for measures Q176 and/or Q337 to discuss revisions for possible implementation of a single all-encompassing measure in future years. However, we agree the changes to measure Q176 do not adequately cover all dermatologic medications seen within measure Q337. For this reason, we will maintain measure Q337 for PY2021.

After consideration of public comments, we are not finalizing the removal of measure Q337 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.7. Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	348
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measures initiative. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple performance periods suggests this is not an important clinical topic for MIPS eligible clinicians.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed removal of measure Q348, citing the removal rationale that there is limited patient population and adoption of the quality measure does not allow for the creation of benchmarks. The commenter indicated that MIPS policies prevent this measure from being used, such as scoring policies that cap the number of performance achievement points that can be earned on measures that lack a benchmark. It also leaves cardiac electrophysiology with only two relevant measures to report and discourages specialty societies from developing new MIPS measures. The commenter discouraged the removal of highly specialized measures that fill an important clinical gap.

Response: We would encourage the commenter to submit comments regarding the MIPS scoring policies. As shown by the continued low adoption rates, measure Q348 is not being implemented by clinicians and a meaningful benchmark cannot be created, meaning this measure is not driving quality care and positive outcomes and is not in alignment with the Meaningful Measure Initiative. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's inability to create a benchmark would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the removal of measure Q348 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.8. Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	390
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the advancements in hepatitis C treatments. There are now curative treatments over an 8-12-week period with few side effects. Additionally, the measure is at risk of capturing "chronic HCV" patients who are no longer viremic, which would not necessitate HCV shared decision making.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter supported the removal of measure Q390 from the MIPS program.

Response: We thank the commenter for supporting the removal of measure Q390.

After consideration of public comments, we are finalizing the removal of measure Q390 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.9.Opioid Therapy Follow-up Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	408
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed removal of measure Q408, stating that opioid treatment agreements ensure that patients have important information regarding potential risks, benefits, and expectations for patient responsibility before using these medications. It is important that clinicians regularly engage patients during opioid treatment, and there are no other measures to achieve this goal. Providers need to continue to educate and follow up with patients regarding their opioid regimens to help combat the opioid crisis. The commenter recommended that this measure be developed further in future rulemaking to include robust evaluation methods.

Several commenters opposed the removal of measure Q408 and stated that following discussion with the measure steward, there are not newer opioid measures to replace the three measures proposed for removal: Q408, Q412, and Q414. The commenters did not agree that these measures do not align with the most recent guidelines and that the measures related to relevant clinical quality activities. Also, without a pain management specialty measure set it is an administrative burden, as there are not an adequate number of quality measures that apply to the specialty of pain management. A commenter cautioned against actions that may limit the current list of quality measures addressing opioid misuse and related issues. Opioid misuse, and substance use disorders more broadly, have become more prevalent during the COVID-19 PHE. CMS must consider additional quality measures that address opioid misuse and related issues to help acknowledge the invaluable work of physicians in addressing such issues among the most vulnerable Medicare beneficiaries.

Response: We thank the commenters for their comments opposing the removal of measure Q408. We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer aligned with current guidelines and is currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, we are finalizing the removal of measure Q408 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.10.Documentation of Signed Opioid Treatment Agreement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	412
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter supported the removal of retired measure Q412 from the MIPS program. as indicated in comments on the Neurology and Geriatrics sets..

Response: We thank the commenter for supporting the removal of measure Q412.

Comment: One commenter opposed removal of measure Q412, stating that opioid treatment agreements ensure that patients have important information regarding potential risks, benefits, and expectations for patient responsibility before using these medications. There are no other measures to achieve this goal. The commenter recommended that this measure be further developed in future rulemaking to include robust evaluation methods.

Several commenters opposed the removal of measure Q412 and stated that following discussion with the measure steward, there are not newer opioid measures to replace the three measures proposed for removal: Q408, Q412, and Q414. The commenters did not agree that these measures do not align with the most recent guidelines and that the measures related to relevant clinical quality activities. Also, without a pain management specialty measure set it is an administrative burden, as there are not an adequate number of quality measures that apply to the specialty of pain management. A commenter cautioned against actions that may limit the current list of quality measures addressing opioid misuse and related issues. Opioid misuse, and substance use disorders more broadly, have become more prevalent during the COVID-19 PHE. CMS must consider additional Quality measures that address opioid misuse and related issues to help acknowledge the invaluable work of physicians in addressing such issues among the most vulnerable Medicare beneficiaries.

Response: We thank the commenters for their comments opposing the removal of measure Q412. We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer aligned with current guidelines and are currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, we are finalizing the removal of measure Q412 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.11.Evaluation or Interview for Risk of Opioid Misuse

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	414
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter supported the removal of retired measure Q414 as indicated in comments on the Neurology and Geriatrics sets. A second commenter was supportive of the proposal to remove 14 quality measures that do not add value to the quality of care, and instead add more meaningful measurements.

Response: We thank the commenters for supporting the removal of measure Q414.

Comment: Several commenters opposed the removal of measure Q414 and stated that following discussion with the measure steward, there are not newer opioid measures to replace the three measures proposed for removal: Q408, Q412, and Q414. The commenters did not agree that these measures do not align with the most recent guidelines and that the measures related to relevant clinical quality activities. Also, without a pain management specialty measure set it is an administrative burden, as there are not an adequate number of quality measures that apply to the specialty of pain management. Another commenter cautioned against actions that may limit the current list of quality measures addressing opioid misuse and related issues. Opioid misuse, and substance use disorders more broadly, have become more prevalent during the COVID-19 PHE. CMS must consider additional Quality measures that address opioid misuse and related issues to help acknowledge the invaluable work of physicians in addressing such issues among the most vulnerable Medicare beneficiaries.

Response: We thank the commenters for their comments opposing the removal of measure Q414. We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer aligned with current guidelines and are currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, we are finalizing the removal of measure Q414 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.12. Quality of Life Assessment for Patients With Primary Headache Disorders

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	435
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion. As there are various tools that providers may choose to use, it difficult to compare measure performance across MIPS eligible clinicians. Additionally, the scores are difficult to capture within the EHR leading to difficulties in determining whether the QoL is being maintained or improving over time.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.
We received no public comments on the removal of this measure; therefore, we are finalizing the removal of measure Q435 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

C.13. Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	437
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 1.854 percent for the MIPS CQMs Specifications collection type and 1.031 percent for the Medicare Part B Claims Measure Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs Specifications collection type and the Medicare Part B Claims Measure Specifications collection type are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter did not support the removal of measure Q437 since reporting difficulties created by the COVID-19 pandemic may limit relevancy of some measures due to reduced services provided. The use of performance period benchmarks for the 2021 performance year introduces uncertainty in measure selection. The removal of this measure would also limit the pool of measures available for radiologists. A second commenter urged CMS to temporarily halt the removal of topped out measures for the 2021 performance year to provide clinicians with consistency as they recover from the COVID-19 PHE, particularly those that may be aligned with future MVPs. A third commenter said removal of this measure would limit the number of measures for radiologists and wanted this topped out measure to remain.

Response: While we acknowledge the hardships faced due to the COVID-19 PHE and the specializations found within radiology the performance for measure Q437 has an extremely high and unvarying performance rate. This does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the removal of measure Q437 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.14. All-Cause Hospital Readmission

Category	Description
NQF # / eCQM NQF #:	1789 / N/A
Quality #:	458
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Administrative Claims
Measure Description:	The 30-day All-Cause Hospital Readmission measure is a risk-standardized readmission rate for beneficiaries age 65 or older who were hospitalized at a short-stay acute care hospital and experienced an unplanned readmission for any cause to an acute care hospital within 30 days of discharge.
Measure Steward:	Yale University
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative to the new measure being proposed in Table A.1. for the 2021 performance period: Table A.1: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups. This proposed new measure is a re-specification of the hospital-level measure and promotes a systems level approach by clinicians, making it a more applicable measure to MIPS eligible clinicians. In the event we did not finalize the proposed new measure: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups, we would have maintained this current measure Q458: All-Cause Hospital Readmission.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.
We received no public comments on this measure proposed for removal; therefore, we are finalizing the removal of measure Q458 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years Comments citing measure Q458, due to the replacement of this measure with new measure Q479, Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups, are addressed under Table A.1.	

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Finalized and Not Finalized for the 2023 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

The D Tables within this final rule provide the substantive changes finalized for the quality measures in CY 2021. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2021 may not be identified within the NPRM due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2021 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2022. The 2021 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library under the measure specifications. For eCQM Release Notes, see the eCQI Resource Center at https://ecqi.healthit.gov/ep-ec?globalyearfilter=2020.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature but we believe are important to communicate to stakeholders. These changes align with the scope of the current coding, however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2021 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes. Language has also been added, to all applicable 2021 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, will the D table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications. **Updated denominator exclusion: For the eCQM Specification collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types:** Revised: Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specification collection type:** Added coding to identify patients with advanced illness and frailty **Updated numerator options: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Stratified the Performance Not Met numerator option into three: **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level < 7.0% **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level greater than or equal to 7.0% and less than 8.0% **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level greater than or equal to 8.0% and less than or equal to 9.0% **Updated numerator instructions: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Added: Do not include HbA1c levels reported by the patient. Added: Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the denominator exclusion language and logic to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. The numerator options for Performance Not Met were stratified to have the ability to better assess hemoglobin A1c levels within the patient population that showed better control. Instructions have been added to ensure the correct patient population as the measure intent is to assess hemoglobin A1c control in Type 1 or Type 2 diabetics and not those patients who have diabetes due to another condition. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: One commenter opposed the proposed changes to the numerator for measure Q001. The removal of patient-reported HbA1cs could increase unnecessary testing for measure compliance. In addition, further clarification on acceptable sources is necessary.

Two commenters did not agree with the proposal to add a third level of stratification to the "Performance Not Met" numerator option *only for the manual MIPS CQM and Medicare Part B Claims collection types.* The commenters stated that by dividing the latter option into two – Most recent hemoglobin A1c (HbA1c) level greater than or equal to 7.0 percent and less than 8.0 percent; and Most recent hemoglobin A1c (HbA1c) level greater than or equal to 8.0 percent and less than or equal to 9.0 percent, CMS is creating additional burden and additional time required to report for administrative staff, particularly those in small and rural practices without an EHR. The commenter is concerned that CMS is making this measure more difficult to complete and report, but only for manual collection types. This creates burden for small and rural practices. In addition, ophthalmology practices have seen a significant reduction in visits due to COVID-19. The commenter urged CMS not to finalize either of these changes. A second commenter stated that having new stratifications means that CMS may not have sufficient data to establish reliable benchmark for this measure for each stratification. In addition, given the fact that CMS proposed to keep this measure in the APP quality measure list, we believe that CMS should keep the measures as are to reduce any further complication already caused by the transition from the current MIPS APM reporting standard to APP reporting. If CMS finalizes this measure with 3 stratifications, the commenter asked that CMS clarify which stratification will be pay-for performance and which will be pay-for reporting measure, and that CMS identify the benchmark for the pay-for performance stratification early in the performance year.

Response: While we understand the desire to ensure there is not unnecessary testing, the measure only requires the assessment of one hemoglobin A1c

Category	Description
	measurement each performance period and it is important to ensure accurate results are documented. The measure steward believes, and we agree, that it is important to have a more granular picture of hemoglobin A1c levels to ascertain the level of control currently being achieved as diabetes is a leading cause of death in the United States. Additionally, there is ongoing discussions regarding acceptable levels of hemoglobin A1c, it is important to obtain this granular information to continue these discussions and drive quality outcomes. With regard to the benchmark, all 'performance not met' numerator options will be combined and removed from the performance rate calculation. The addition of these stratifications will have no bearing on the ability to create a reliable benchmark for the measure. We encourage the commenter to communicate this request to the measure steward for consideration in future years. After consideration of public comments, we are finalizing the changes to measure Q001 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality#:	005
CMS eCQM ID:	CMS135v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated the denominator exception logic**: **For the eCQM Specifications collection type:** Added sacubitril in the Allergy/Intolerance logic. **Updated denominator: For all collection types:** Submission Criteria 1: Added telehealth as eligible for all encounters.
Steward:	
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to include sacubitril in the Allergy/Intolerance logic as this is one of the components of ARNI and an allergy to this ingredient would be a clinically appropriate reason for allowing a denominator exception for this patient population. We proposed to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenters supported the addition of telehealth reporting for measure Q005.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q005 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of additional telehealth encounter eligibility for eCQM Specifications collection type as this is already in the current measure.

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
NQF # / eCQM NQF #:	0067 / N/A
Quality#:	006
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q006.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q006 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.4 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.
Substantive Change:	**Updated logic: For the eCQM Specifications collection type:** Added constraint to measure logic in instances when the patient has both prior (within the past 3 years) MI and LVEF < 40%. **The guidance is revised to read: For the eCQM Specifications collection type:** Beta-blocker therapy: - For patients with prior MI, beta-blocker therapy includes any agent within the beta-blocker drug class. As of 2015, no recommendations or evidence are cited in current stable ischemic heart disease guidelines for preferential use of specific agents - For patients with prior LVEF <40%, beta-blocker therapy includes the following: bisoprolol, carvedilol, or sustained release metoprolol succinate. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. A range value should satisfy the logic requirement for 'Ejection Fraction' as long as the ranged observation value clearly meets the less than 40% threshold noted in the denominator logic. A range that is inclusive of or greater than 40% would not meet the measure requirement. If a patient has had a myocardial infarction (MI) within the past 3 years and a current or prior LVEF < 40% (or moderate or severe LVSD), the patient should only be counted in Population Criteria 1. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. Beta-blocker therapy: **The instructions are revised to read: For the MIPS CQMs Specifications collection type**: This measure is to be submitted a minimum of once per performance period for all patients with a diagnosis of CAD seen during the performance period. Only patients who had at least two denominator-eligible visits during the performance period will be counted for Submission Criteria 1 and Submission Criteria 2 of this measure. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure for the primary management of patients with CAD based on the services provided and the measure-specific denominator coding. The MIPS eligible clinician should submit data on one of the submission criteria, depending on the clinical findings. If the patient has CAD or history of cardiac surgery and a current or prior LVEF < 40% (or moderate or severe LVSD), use Submission Criteria 1. If the patient has CAD or history of cardiac surgery and has a prior (within the past 3 years) MI, use Submission Criteria 2. The 3-year lookback period for the prior MI should be from the time of the encounter that is used to qualify for the denominator and evaluate the numerator. If the patient has had an MI within the past 3 years and has a current or prior LVEF < 40% (or moderate or severe LVSD), the MIPS eligible clinician should submit quality-data codes for Submission Criteria 1 and this will count as appropriate submission for this patient. **Updated denominator criteria: For all collection type:** Added telehealth as eligible for all encounters. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Denominator Criteria One: Revised: Left ventricular ejection fraction (LVEF) < 40% or documentation of moderate or severe LVSD. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication.
Steward:	
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type logic to improvement alignment with measure intent as it will add constraints to help prevent double counting of patients who had both a myocardial infarction and LVEF < 40% within the past 3 years. Additionally, the guidance was revised to help clarify which population eligible patients should be included for the purposes of this measure. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. For both the eCQM Specifications and MIPS CQMs Specifications collection types, the guidance and instructions have been updated, respectively, to add moderate or severe LVSD as a proxy for LVEF < 40%. The measure steward's Technical Expert Panel (TEP) determined that moderate or severe LVSD is an appropriate proxy and aligns with the intent of the measure. We agreed with this addition as LVSD can be "defined as a left ventricular ejection fraction less than 40 percent or a narrative description consistent with moderate or severe systolic dysfunction." (Per the Joint Commission Specifications Manual (v2018A)). Additionally, we proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenters supported the addition of telehealth reporting for measure Q007.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

Category	Description
After consideration of public comments, we are finalizing the changes to measure Q007 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LSVD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality#:	008
CMS eCQM ID:	CMS144v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated denominator: For all collection types:** Submission Criteria 1: Added telehealth as eligible for all encounters. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to revise the 'Medical Reason' value set for the eCQM Specifications collection type based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception.

Comment: Several commenters supported the addition of telehealth reporting for measure Q008.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q008 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of additional telehealth encounter eligibility for eCQM Specifications collection type as this is already in the current measure.

D.6 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

Category	Description
NQF # / eCQM NQF #:	0086 / 0086e
Quality#:	012
CMS eCQM ID:	CMS143v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.
Substantive Change:	**Modified collection type:** eCQM Specifications **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types as they have reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the eCQM Specifications collection type, as such, the measure will be retained for this collection type. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

Comment: One commenter opposed CMS's proposal to remove the Medicare Part B Claims Measure Specifications collection type for measure Q012 because it would adversely impact ophthalmologists, particularly those in small and rural practices who must rely on the claims reporting collection type because they cannot afford to adopt CEHRT. The commenter recognized the topped out status under the claims and MIPS CQM collection types, but removing this measure entirely from the claims collection type will result in even fewer measures relevant to ophthalmologists' scope of practice.

Response: We strive to ensure that all measures align with the Meaningful Measures Initiative, including the removal of measures that are at the end of the topped out lifecycle. Additionally, by removing collection types at the end of the topped out lifecycle, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the changes to measure Q012 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.7 Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
NQF # / eCQM NQF #:	0087 / N/A
Quality#:	014
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.
Substantive Change:	**Updated numerator definition: For all collection types:** Revised: Severity of Macular Degeneration – Early, intermediate and advanced; or active choroidal neovascularization, inactive choroidal neovascularization, or with inactive scar.
Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the definition referencing the clinical stages for the 'Severity of Macular Degeneration' to clarify and align the concept with ICD-10 terminology. Adding clarity that these codes are clinically relevant and applicable.

Comment: One commenter supported updating the definition referencing the clinical stages for the 'Severity of Macular Degeneration' to clarify and align the concept with ICD-10 terminology.

Response: We thank the commenter for supporting the change to this measure.

After consideration of public comments, we are finalizing the changes to measure Q014 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.8 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	019
CMS eCQM ID:	CMS142v9
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**Update numerator logic: For the eCQM Specifications collection type**: Removed "sender" and "recipient" attributes. **Updated value set/coding: For the eCQM Specifications collection type**: Removed "sender" and "recipient" attributes. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the "sender" and "recipient" attributes from the numerator logic and the value set/coding of the eCQM Specifications collection type and reverted to the numerator logic from performance year 2019. These attributes increased burden and were difficult to implement. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

Comment: One commenter supported CMS's proposed removal of "sender" and "recipient" attributes. This will decrease burden and make the measure technically easier to report. The commenter also supported the proposed removal of denominator exception "Medical Reason" codes as they are inappropriate for this measure.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q019 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.9 Advance Care Plan

Category	Description
NQF # / eCQM NQF #:	0326 / N/A
Quality#:	047
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Substantive Change:	**Updated denominator: For all collection types:** Added clinical social worker clinician type.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add the clinical social worker clinician type to the denominator eligible encounters as this clinical concept is applicable to their scope of practice since these clinicians are integral to ensuring patients have up to date advance care plans and/or surrogate decision makers documented within the medical record.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q047 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.10 Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy

Category	Description
NQF # / eCQM NQF #:	0102 / N/A
Quality#:	052
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	American Thoracic Society
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. As captured in the 2020 Benchmark File, this collection type also has high performance rate. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q052 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.11 Appropriate Treatment for Children with Upper Respiratory Infection (URI)

Category	Description
NQF # / eCQM NQF #:	0069 / N/A
Quality#:	065
CMS eCQM ID:	CMS154v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.
Substantive Change:	**The title is revised from 'Appropriate Treatment for Children with Upper Respiratory Infection (URI)' to:** Appropriate Treatment for Upper Respiratory Infection (URI) **The description is revised to read:** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event. **The initial patient population is revised to read: For the eCQM Specifications collection type:** Outpatient visits, telephone visits, online assessments, observation stays or emergency department visits with a diagnosis of URI during the measurement period among patients 3 months of age and older. **Updated stratification: For the eCQM Specifications collection type:** 3 months-17 years, 18-64 years, 65 years and older. **The guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period This eCQM is an episode-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The denominator is revised to read: For the MIPS CQMs Specifications collection type:** Outpatient visits, telephone visits, online assessments, observation stays or emergency department visits with a diagnosis of upper respiratory infection (URI) during the measurement period among patients 3 months of age and older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Revised: Patients aged 3 months of age and older on date of encounter. Revised denominator eligible coding to include telehealth with qualified nonphysician health care professional. **The denominator instruction is revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. If the patient has more than one episode in a 31-day period, include only the first episode. **Updated denominator exclusion:** **For the eCQMs Specifications collection type:** Added: 1. Exclude URI episodes when the patient had a competing comorbid condition during the 12 months prior to or on the episode date. Revised: 1. Exclude URI episodes when the patient had a new or refill prescription of antibiotics in the 30 days prior to or on the episode date. 2. Exclude URI episodes when the patient had competing diagnosis on or 3 days after the episode date. 3. Exclude URI episodes when the patient had hospice care overlapping with the measurement period. **For MIPS CQMs Specifications collection type:** Added: 1. URI episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). 2. URI episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to or on the episode date. Revised: 1. URI episodes when the patient had competing diagnoses on or 3 days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, acute pharyngitis, acute tonsillitis, chronic sinusitis, infection of the pharynx/larynx/tonsils/adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI, and acne). Removed: 1. Children who are taking antibiotics in the 30 days prior to the date of the encounter during which the diagnosis was established. **The numerator is revised to read:** **For the eCQMs Specifications collection type:** URI episodes without a prescription for antibiotic medication on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection. **For the MIPS CQMs Specifications collection type:** URI episodes without a prescription for antibiotic medication (from Table 1) on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection. **The numerator instruction is revised to read: For the MIPS CQMs Specifications collection type:** For performance, the measure will be calculated as the number of patient's encounter(s) where antibiotics from Table 1 were neither prescribed nor

Category	Description
	dispensed on or within 3 days of the episode for URI over the total number of encounters in the denominator. A higher score indicates appropriate treatment of patients with URI (e.g., the proportion for whom antibiotics were not prescribed or dispensed following the episode). Delayed prescriptions (where an antibiotic was prescribed and patient was instructed to delay taking the antibiotic) are considered "Performance Not Met". Table 1 - Antibiotic Medications Note: This list should be used when assessing antibiotic prescriptions for the denominator exclusion and numerator components. Revised: Table 1 – Antibiotic Medication: Added Penicillin G benzathine and removed 'Miscellaneous Antibiotics Category' (Erythromycin-sulfisoxazole) **Updated value set: For the eCQM Specifications collection type:** Added 'Aggressive periodontitis' to the value set for competing diagnosis. Added telehealth services value set to eligible encounters.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding overuse of antibiotics are not limited to the pediatric population. This will allow for clinicians to report on both pediatric and adult patients. The denominator instructions and guidance are revised to clarify that only the first episode should be included if a patient has multiple episodes in a 31-day period. The denominator exclusions have been updated to reflect the change in age range and to align language with the measure submission frequency. Additionally, a denominator exclusion has been added to remove patients with competing comorbid conditions from the denominator population as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. The numerator note for the MIPS CQMs Specifications collection type was updated to clarify use of delayed prescriptions and the antibiotic medication table. Given the intent of the measure is to assess appropriate antibiotic use, delayed prescriptions will be considered numerator non-compliant as this would still constitute prescribing an antibiotic. The antibiotic medication table was also updated to be clinically relevant. The eCQM Specifications collection type value set for competing diagnosis was updated to include aggressive periodontitis as it is clinically relevant to the denominator exclusion intent. Additionally, a telehealth services value set was added to the eligible encounters for a more complete patient population.

We proposed a substantive change to the Numerator for the MIPS CQMs Specifications collection type: however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
URI episodes without a prescription for antibiotic medication (Table 1) on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection.

This additional refinement of revising '(from Table 1)' to '(Table 1)' does not affect the intent of the proposed substantive change.

Comment: One commenter stated that placing an acute and transient diagnosis on the patient problem list has the potential to inappropriately identify URI encounters because problem lists do not have expiration dates. The commenter recommended that a URI is an acute diagnosis that should only be captured as a visit diagnosis. The commenter also stated that antibiotics ordered without an end date have the potential to be included in the measure even if the antibiotic order was placed months prior to the URI encounter. The commenter recommended that the logic should not look at any antibiotics outside of the 30 day window.
Response: We thank the commenter for their comment. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q065 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.12 Appropriate Testing for Children with Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	066
CMS eCQM ID:	CMS146v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.
Substantive Change:	**The title is revised from 'Appropriate Testing for Children with Pharyngitis' to:** Appropriate Testing for Pharyngitis **The description is revised to read:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test. **The guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. This eCQM is an episode-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The initial patient population is revised to read: For the eCQM Specifications collection type:** Outpatient, telephone, online assessment, observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispensing event among patients 3 years or older. **The denominator is revised to read: For the MIPS CQMs Specifications collection type**: Outpatient, telephone, online assessment, observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispending event among patients 3 years or older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type**: Revised denominator eligible coding to include telehealth with qualified nonphysician health care professional. **The denominator instructions are revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. If a patient has more than one eligible episode in a 31-day period, include only the first eligible episode. **Updated denominator exclusion:** **For the eCQMs Specifications collection type:** Added: 1. Exclude episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date. Revised: 1. Exclude episodes where the patient is taking antibiotics in the 30 days prior to the episode date. 2. Exclude episodes when the patient had hospice care overlapping with the measurement period. 3. Exclude episodes where the patient had a competing diagnosis within 3 days after the episode date. **For MIPS CQMs Specifications collection type:** Added: 1. Episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). Revised: 1. Episodes where the patient is taking antibiotics (Table 1) in the 30 days prior to the episode date. 2. Episodes where the patient had a competing diagnosis within 3 days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, chronic sinusitis, infection of the pharynx/larynx/tonsils/adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI). **Updated Table 1: For the MIPS CQMs Specifications collection type:** Added: Note: This list should be used when assessing antibiotic prescriptions for the denominator and denominator exclusion components. Revised: Table 1 – Antibiotic Medication: Added Penicillin G benzathine and removed 'Miscellaneous Antibiotics Category' (Erythromycin-sulfisoxazole) **The numerator is revised to read: For all collection types**: A group A streptococcus test in the 7-day period from 3 days prior to the episode date through 3 days after the episode date. **Updated stratification**: **For the eCQM Specifications collection type:** 3-17 years, 18-64 years, 65 years and older. **Updated value set: For the eCQM Specifications collection type:** Added telehealth services value set to eligible encounters.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding appropriate testing are not limited to the pediatric population. This will allow for clinicians to report on both pediatric and adult patients. The denominator instructions and guidance are revised to clarify that only the first episode should be included if a patient has multiple episodes in a 31-day period. The denominator exclusions have been updated to reflect the change in age range and to align language with the measure submission frequency. Additionally,

Category	Description
	a denominator exclusion has been added to remove patients with competing comorbid conditions from the denominator population as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. For the MIPS CQMs Specifications collection type, Table 1 was updated to remain clinically relevant and a note was added to clarify usage of Table 1 for the purposes of this measure. The eCQM Specifications collection type value set for competing diagnosis was updated to include aggressive periodontitis as it is clinically relevant to the denominator exclusion intent. Additionally, a telehealth services value set was added to the eligible encounters for a more complete patient population.
We proposed a substantive change to the denominator exclusion for the MIPS CQMs Specifications collection type: however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Added: 1. Episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). Revised: 1. Episodes where the patient is taking antibiotics (Table 1) in the 30 days prior to the episode date. 2. Episodes where the patient had a competing diagnosis within three days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, chronic sinusitis, infection of the adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI) This additional refinement of language within the competing diagnosis exclusion does not affect the intent of the proposed substantive change, but removes the duplication in denominator eligible clinical encounters that present with a bacterial infection therefore allowing reporting eligible clinicians to report a denominator exclusion for these patients would not influence overall performance of the measure. We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q066 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.13 Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	654/N/A
Quality#:	093
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Substantive Change:	**Updated denominator: For all collection types**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Two commenters supported the addition of telehealth reporting for measure Q093.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q093 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.14 Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 0104e
Quality#:	107
CMS eCQM ID:	CMS161v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.
Substantive Change:	**The description is revised to read:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit. **Updated guidance:** Added: In recognition of the growing use of integrated and team-based care, the diagnosis of dementia and the assessment of cognitive function need not be performed by the same provider or clinician. **The initial patient population is revised to read:** Patient visits during which a new diagnosis of MDD, single or recurrent episode, was identified. **The numerator is revised to read:** Patient visits during which a new diagnosis of MDD, single or recurrent episode, was identified and a suicide risk assessment was completed during the visit.
Steward:	Mathematica
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the description, initial patient population, and numerator language to better align with the measure intent and clarify that the measure is episodic in nature. The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agreed that this guidance update is clinically appropriate and aligns better with clinical care workflows.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q107 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.15 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / 0041e
Quality#:	110
CMS eCQM ID:	CMS147v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated guidance: For the eCQM Specifications collection type:** Revised: Due to the changing stance of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians to review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. Should the LAIV be recommended for administration for a particular flu season, eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting either previous receipt or using the CVX 88 for unspecified formulation, 2) report a denominator exception, either as a patient reason (e.g., for patient preference) or a system reason (e.g., the institution only carries LAIV). This is a patient-based measure. **Updated denominator note: For the Medicare Part B Claims Measure Specifications collection type:** Added: For the purposes of the program, to submit on the flu season 2020-2021, the patient must have a qualifying encounter between January 1 and March 31, 2021. to submit on the flu season 2021-2022, the patient must have a qualifying encounter between October 1 and December 31, 2021. A qualifying encounter needs to occur within the flu season that is being submitted; any additional encounter(s) may occur at any time within the measurement period. **Updated denominator exception: For the eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. Updated denominator: For all collection types: Added telehealth as eligible encounter.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator note for the Medicare Part B Claims Measure Specifications collection type to add clarity and align the language with the MIPS CQMs Specifications collection type. We proposed to update the guidance for the eCQM Specifications collection type to better align with the updated CDC/ACIP clinical guidelines and to clarify the intent of the measure. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

We proposed a substantive change to the Denominator Note for the Medicare Part B Claims Measure Specifications collection type; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: For the purposes of the program, in order to submit on the flu season 2020-2021, the patient must have a qualifying encounter between January 1 and March 31, 2021. In order to submit on the flu season 2021-2022, the patient must have a qualifying encounter between October 1 and December 31, 2021. A qualifying encounter needs to occur within the flu season that is being submitted; any additional encounter(s) may occur at any time within the measurement period.

This additional refinement of including the language 'in order' preceding the instance of 'to submit' within the proposed language does not affect the intent of the proposed substantive change.

Comment: One commenter supported the addition of telehealth reporting for measure Q110.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

Comment: One commenter did not support the addition of telehealth reporting for measure Q110.

Response: We believe that it is important to ensure all patients have received an influenza vaccine as this is critical to the community and population health. It is important to have a complete denominator patient population to assess numerator compliance, which should include those encounters that occur via telehealth.

Category	Description
After consideration of public comments, we are finalizing the changes to measure Q110 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications. In addition, we are not finalizing the proposed additional telehealth encounter eligibility substantive change for the eCQM Specifications collection type because this is already specified in the current measure.	

D.16 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed logic and value set related to unilateral mastectomy. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised**:** Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications collection type and the MIPS CQMs Specifications collection type:** Added coding to identify patients with advanced illness and frailty
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection, we proposed removing the logic and value set related to unilateral mastectomy to ensure that all patients with existing breast tissue are included in the initial patient population as it is important they receive screening for breast cancer on remaining breast tissue. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: One commenter had concerns about removing unilateral mastectomy from the mammogram quality measure. Current specifications clarify that both a right and left unilateral must be completed to count as an exclusion. The commenter saw no reason to remove that logic, as it still accomplishes what CMS is asking for by ensuring that, "all patients with existing breast tissue are included in the initial patient population as it is important they receive screening for breast cancer on remaining breast tissue." A second commenter requested that CMS provide clarification on the statement "Removed logic and value set related to unilateral mastectomy," as the commenter believed the intent of this statement is unclear.

Response: This revision was made to ensure that the logic is in alignment with the measure intent. As the logic is currently, a patient would be excluded if they had two unilateral mastectomy codes. However, it is possible for a patient to have two partial mastectomies on the same breast. Therefore, instances of mastectomies without indication of right or left side are being removed to increase specificity and ensure only those patients with total mastectomies are excluded. This will capture a more complete patient population for the assessment of the quality action and ensure patients with existing breast tissue are screened for breast cancer.

After consideration of public comments, we are finalizing the changes to measure Q112 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.

D.17 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: 1. Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. 2. Exclude patients with a diagnosis or past history of total colectomy or colorectal cancer. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator criteria: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types**: Removed coding not applicable to preventive value sets. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added coding to identify patients with advanced illness and frailty.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection type We also proposed to revise the language for the exclusion for diagnosis or past history of total colectomy or colorectal cancer for clarity and to align with the other denominator exclusions. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We proposed to remove denominator eligible coding that is not applicable to a preventive value set and may not be appropriate for inclusion in the measure's denominator eligible patient population. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q113 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.	

D.18 Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis

Category	Description
NQF # / eCQM NQF #:	0058 / N/A
Quality#:	116
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.
Substantive Change:	**The title is revised from 'Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis' to:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis. **The description is revised to read:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event. **The instructions are revised to read:** This measure is to be submitted at each occurrence of acute bronchitis/bronchiolitis during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The denominator is revised to read:** All patients aged 3 months or older with an outpatient, telephone visit, online assessment, observation visit or emergency department (ED) visit with a diagnosis of acute bronchitis/bronchiolitis during the measurement period. **Updated denominator criteria:** Revised: Patients 3 months of age and older on date of encounter. Added: Diagnosis for bronchiolitis. **Updated denominator exclusion:** Revised: 1. Outpatient, ED or Observation visits that result in an inpatient admission. Added: 2. Acute bronchitis/bronchiolitis episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to or on the episode date. **The denominator note is revised to read:** Do not include outpatient, ED or observation visits that result in an inpatient admission. When an outpatient, ED or observation visit and an inpatient stay are billed on separate claims, the visit results in an inpatient stay when the outpatient/ED/observation date of service occurs on the day prior to the admission date or any time during the admission (admission date through discharge date). An outpatient, ED or observation visit billed on the same claim as an inpatient stay is considered a visit that resulted in an inpatient stay. **The numerator instructions are revised to read:** For performance, the measure will be calculated as the number of patient encounters where antibiotics were neither prescribed nor dispensed on or within 3 days of the episode for acute bronchitis/bronchiolitis over the total number of encounters in the denominator (patients aged 3 months and older with an outpatient, telephone, online assessment, observation or ED visit for acute bronchitis/bronchiolitis). A higher score indicates appropriate treatment of patients with acute bronchitis/bronchiolitis (e.g., the proportion for whom antibiotics were not prescribed or dispensed on or 3 days after the encounter). Delayed prescriptions (where an antibiotic was prescribed and patient was instructed to delay taking the antibiotic) are considered "Performance Not Met". **Updated numerator instructions:** Added: Note: This list should be used when assessing antibiotic prescriptions for the denominator exclusion and numerator components. Removed "Norfloxacin" from Table 1 – Antibiotic Medications.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding appropriate use of antibiotics are not limited to the adult population. This will allow for clinicians to report on both pediatric and adult patients. The title, description, instructions, and denominator are also being revised to include the diagnosis of bronchiolitis as denominator eligible to better align with the broadened age range as bronchiolitis is more commonly seen in babies and children. The diagnosis is clinically relevant to the intent of this measure. The denominator exclusion and denominator note are revised to better clarify that all visits resulting in an inpatient admission should be excluded as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. The numerator instructions have been updated to align language with the denominator patient population updates, as well as to clarify that delayed prescriptions are still considered to be a "Performance Not Met" as the clinician is still prescribing or dispensing a prescription, which does not align with the measure's intent.

We proposed a substantive change to the denominator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
All patients aged 3 months or older with an outpatient visit, telephone visit, online assessment, observation visit or emergency department (ED) visit with a diagnosis of acute bronchitis/bronchiolitis during the measurement period.

This additional refinement of 'outpatient' to 'outpatient visit' does not affect the intent of the proposed substantive change.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q116 as indicated for

Category	Description
the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.19 Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality#:	117
CMS eCQM ID:	CMS131v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications:** Revised: Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added coding to identify patients with advanced illness and frailty. **The numerator options are revised to read: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** **Performance Met:** • Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed. • Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy. • 7 standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed. • 7 standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy. • Eye imaging validated to match diagnosis from 7 standard field stereoscopic photos results documented and reviewed. • Eye imaging validated to match diagnosis from 7 standard field stereoscopic photos results documented and reviewed, without evidence of retinopathy. • Low risk for retinopathy (no evidence of retinopathy in the prior year)*. **Performance Not Met:** • Dilated eye exam was not performed, reason not otherwise specified. **Updated numerator options note: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Removed: **Note: For Performance Year 2020 reporting, the Centers for Medicare & Medicaid Services and the American Medical Association have approved the use of the 8P modifier with HCPCS codes to report the Performance Not Met numerator option for Quality ID #117.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. The numerator options are being updated to stratify numerator compliant patients into those who are complaint and those who are compliant with evidence of retinopathy. This granularity will give a better picture of the patient population and the percentage of those patients who did not have evidence of retinopathy, and may fall into low risk for retinopathy, for the purposes of this measure. The numerator option note associated with the "Performance Not Met" option is being removed as it will not be applicable as the numerator options are being updated.

Comment: One commenter supported the inclusion of this measure for 2021 MIPS participants, but urged CMS to ensure that application of the measure is consistent with NCQA's update to this measure in its 2021 measure set, namely, NCQA's clarification that "eye exam results read by a system that provides an artificial intelligence (AI) interpretation meet criteria," as stated in NCQA's changes to HEDIS MY 2020 and MY 2021. The commenter is concerned that, absent this clarification, there will be confusion for practitioners who participate in MIPS and read the measure to require an eye exam by an "eye care professional," as indicated in CMS' table of Previously Finalized Measures in the Family Medicine Set for MIPS measure Q117. Such a clarification would also be consistent with the American Diabetes Association (ADA) 2020 standards for diabetes care, which provide, "Artificial intelligence systems that detect more than mild diabetic retinopathy and diabetic macular edema authorized for use by the FDA represent an alternative to traditional screening approaches."

Response: We support technology that enhances a clinician's ability to diagnosis and treat patients safely and efficiently. Annually, we collaborate with measure stewards to gather revisions and incorporate them into the MIPS quality measures to ensure the program reflects the most recent version of the specification. We are not responsible to ensure the revisions provided by the measure steward align with specifications outside of MIPS. Additionally, there may be timing considerations for revisions to be updated within MIPS that did not allow the measure steward to align the MIPS version of the specification to the HEDIS specification. We believe that we captured the measure steward's intent for this measure for this performance period. We believe by stratifying the numerator options, more granular data can be captured to discern between patients with and without evidence of retinopathy. This information may give insight into those patients with controlled blood sugar and those with uncontrolled blood sugar. We encourage the commenters to collaborate with the measure steward regarding the request of further stratification of the numerator for this measure to be considered for future years.

Category	Description
	Comment: One commenter opposed the changes to the numerator for measure Q117. CMS proposed to add stratification to the "Performance Met" numerator option *only for the manual MIPS CQM and Medicare Part B Claims collection types.* The commenter stated that currently, "Performance Met" includes the following four options: G2102 Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed Or; G2103 Seven standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed Or; G2104 Eye imaging validated to match diagnosis from seven standard field stereoscopic photos results documented and reviewed; Or 3072F Low risk for retinopathy (no evidence of retinopathy in the prior year). CMS is proposing to add further stratification by dividing the first three of these current options into two each – one as currently written and a second with "; without evidence of retinopathy" addended to the end of the option description. The commenter stated that not only is this information irrelevant to the measure, but CMS is also creating significant additional burden by nearly doubling the number of classifications that manual reporters must organize patients into in order to report the measure. This created burden on small and rural practices without an EHR, which also concerning due to COVID-19. The commenter urged CMS not to finalize this additional stratification of the numerator options for measure Q117. **Response:** We support technology that enhances a clinician's ability to diagnosis and treat patients safely and efficiently. Annually, we collaborate with measure stewards to gather revisions and incorporate them into the MIPS quality measures to ensure the program reflects the most recent version of the specification. We believe that we captured the measure steward's intent for this measure for this performance period. We believe by stratifying the numerator options, more granular data can be captured to discern between patients with and without evidence of retinopathy. This information may give insight into those patients with controlled blood sugar and those with uncontrolled blood sugar. We encourage the commenters to collaborate with the measure steward regarding the request of further stratification of the numerator for this measure to be considered for future years. After consideration of public comments, we are finalizing the changes to measure Q117 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.20 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0066 / N/A
Quality#:	118
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.
Substantive Change:	**Updated denominator criteria**: Added: Eligible coding for the additional patient encounter is identical to 'Patient encounter during the performance period' criteria. **Updated denominator:** Added telehealth as eligible for all encounters.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. Additionally, we proposed to clarify the denominator eligible coding for the two visits necessary for denominator eligibility.

Comment: One commenter supported the addition of telehealth reporting for measure Q118.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q118 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.21 Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality#:	119
CMS eCQM ID:	CMS134v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Substantive Change:	**Updated denominator: For the eCQM Specifications collection type:** Revised**:** Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic**: **For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the MIPS CQMs Specifications collection type:** Revised**:** Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period **Updated denominator exclusion: For the MIPS CQMs Specifications collection type**: Added coding to identify patients with advanced illness and frailty.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q119 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.22 Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation

Category	Description
NQF # / eCQM NQF #:	0417 / N/A
Quality#:	126
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.
Substantive Change:	**Updated denominator exception:** Added: Clinician documented that patient had medical reason for not performing lower extremity neurological exam.
Steward:	American Podiatric Medical Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a denominator exception for patients with medical reasons for not performing a lower extremity neurological exam. As there may be instances where a patient is denominator eligible, however, a lower extremity neurological exam would not be reasonably performed due the presence of a burn, ulceration, or infection, for example. Adding this denominator exception allows the MIPS eligible clinician to exercise their clinical judgement as to when it is not feasible to perform a lower extremity neurological exam.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q126 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.23 Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear

Category	Description
NQF # / eCQM NQF #:	0416 / N/A
Quality#:	127
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.
Substantive Change:	**Updated denominator exclusion:** Added: Clinician documented that patient was not an eligible candidate for evaluation of footwear as patient is bilateral lower extremity amputee.
Steward:	American Podiatric Medical Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a denominator exclusion for bilateral lower extremity amputee as this patient population is not applicable to this measure and should not be included in the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q127 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.24 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	128
CMS eCQM ID:	CMS69v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m2.
Substantive Change:	**The description is revised to read:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous 12 months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters. **Updated guidance: For the eCQM Specifications collection type:** Removed: Review the following to apply the Medical Reason exception criteria: The Medical Reason exception could include, but is not limited to, the following patients as deemed appropriate by the health care provider: * Elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as the following examples: * Illness or physical disability * Mental illness, dementia, confusion * Nutritional deficiency such as Vitamin/mineral deficiency * Patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status Revised: See denominator exception section for examples. **Updated definition: For all collection types:** Added**:** Normal BMI Parameters – Age 18 years and older BMI >= 18.5 and < 25 kg/m2 **For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Not Eligible for BMI Calculation or Follow-Up Plan (Denominator Exclusion) – A patient is not eligible if one or more of the following reasons are documented: • Patients receiving palliative or hospice care on the date of the current encounter or any time prior to the current encounter • Patients who are pregnant on the date of the current encounter or any time during the measurement period prior to the current encounter Patients with no documented BMI or a documented BMI outside normal parameters and a documented reason for not completing BMI follow-up plan during the current encounter or within the previous 12 months of the current encounter (Denominator Exception) – • Patients with a documented medical reason for not documenting BMI or for not documenting a follow-up plan for a BMI outside normal parameters (e.g., elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as illness or physical disability, mental illness, dementia, confusion, or nutritional deficiency such as vitamin/mineral deficiency; patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status) • Patients who refuse measurement of height and/or weight on the date of the current encounter or any time during the measurement period prior to the current encounter **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed: Patients who refuse measurement of height and/or weight. Added: Hospice care value sets **Updated denominator exception:** **For the eCQM Specifications collection type:** Added: Patients who refuse measurement of height and/or weight. Revised: Patients with a documented medical reason for not documenting BMI or for not documenting a follow-up plan for a BMI outside normal parameters (e.g., elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as illness or physical disability, mental illness, dementia, confusion, or nutritional deficiency such as vitamin/mineral deficiency; patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). **For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection type:** Added: BMI not documented due to medical reason OR patient refusal of height or weight measurement. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process

Category	Description
Rationale:	We proposed to update the measure description language to reduce redundancy throughout the specification and clarify the intent. The guidance for the eCQM Specifications collection type was updated to move the medical reason exception language to the denominator exceptions header as this language is more suitable for this field. The definition for "Normal BMI Parameters" was moved to the definition section as it is more applicable here and helps readability. During the change review process, the patient refusal denominator exclusion was moved to the denominator exception. We agreed that patient refusal is more appropriately classified as a denominator exception as the patient would still be denominator eligible. For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type, the definitions for the denominator exclusion and denominator exception were updated to reflect the changes and to align language across collection types. Additionally, a denominator exception was added to reflect the definition revisions and capture patients for whom BMI was not documented due to medical reasons or patient refusal. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

We proposed a substantive change to the description; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.

This additional refinement of spelling out of the number 12 does not affect the intent of the proposed substantive change.

Comment: One commenter indicated that the BMI range is too narrow (60 percent US adults is above 25) and is not practical as many practitioners do not begin to discuss weight management with patients until the BMI is around 29. Widening the BMI range will begin to capture the a more targeted population. The commenter asked stated that higher BMI ranges get consumed with other conditions so weight is not addressed for the BMI alone but for co-existing conditions (diabetes, GI etc.). The commenter recommended that an exclusion be provided for other conditions involving weight management.

Response: We thank the commenter for their comment. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years. Part of the Meaningful Measures Initiative is to align with current medical guidelines and implementing measures the drive quality care, reduce risk factors, and promote positive patient outcomes.

Comment: One commenter stated that measure Q128 requires clinicians to measure patients' height and weight and establish a goal. However, significant weight loss is unreasonable during the relatively short length of stay for patients requiring rehabilitation services. The collection of this information therefore serves no role for the patient during their course of care and in the calculation of Medicare's payment for therapy services.

Response: We thank the commenter for their comment. We agree that a patient may not have enough time to experience significant weight loss while receiving rehabilitation services. Although, the intent of the measure is provide a follow-up plan for patients that have a body mass index (BMI) outside normal parameters. The follow-up may include a referral to, for example, a Registered Dietitian Nutritionist (RDN), occupational therapist, physical therapist, primary care provider, exercise physiologist, mental health professional, or surgeon), for lifestyle/behavioral therapy and/or exercise counseling which could support the patient after discharge from rehabilitation services.

After consideration of public comments, we are finalizing the changes to measure Q128 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.25 Documentation of Current Medications in the Medical Record

Category	Description
NQF # / eCQM NQF #:	0419 / 0419e
Quality#:	130
CMS eCQM ID:	CMS68v10
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.
Substantive Change:	**The description is revised to read: For all collection types:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. **The guidance is revised to read: For the eCQM Specifications collection type**: This eCQM is an episode-based measure. This measure is to be reported for every encounter during the measurement period. Eligible professionals or eligible clinicians reporting this measure may document medication information received from the patient, authorized representative(s), caregiver(s) or other available healthcare resources. This list must include all known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration. This measure should also be reported if the eligible professional or eligible clinician documented the patient is not currently taking any medications. By reporting the action described in this measure, the provider attests to having documented a list of current medications utilizing all immediate resources available at the time of the encounter. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The denominator exception is revised to read: For the eCQM Specifications collection type:** Documentation of a medical reason(s) for not documenting, updating, or reviewing the patient's current medications list (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). **The numerator is revised to read: For all collection types:** Eligible professional or eligible clinician attests to documenting, updating or reviewing the patient's current medications using all immediate resources available on the date of the encounter. **Updated numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: This list must include ALL known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration. **Updated denominator exception: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection type:** Revised**:** Documentation of a medical reason(s) for not documenting, updating, or reviewing the patient's current medications list (e.g., patient is in an urgent or emergent medical situation).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description to remove language that is more appropriate for the guidance/notes sections of the measure specification. This will help with measure intent, clarity, and readability. The guidance for the eCQM Specifications collection type has been updated to clarify the intent of the measure. The intent is to document all known prescriptions, since the measure steward believes that MIPS eligible clinician should not be held accountable for information that is not available utilizing all immediate resources. The denominator exception was updated in all collection types to add clarity regarding use of the denominator exception and to align the language throughout the specification. The numerator notes for the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types was updated with information removed from the description. This information outlines what is necessary for numerator compliance and is better suited for the numerator notes section for ease of use.

Comment: One commenter supported CMS's proposal to update the measure description to clarify that clinicians must only document all known medications and that clinicians should not be held accountable for information that is not available utilizing all immediate resources. This clarification will decrease burden on MIPS eligible clinicians reporting this measure.

Response: We thank the commenter for supporting the change to this measure.

Comment: One commenter stated that inclusion of the Dialysis SNOMED code creates a burden for Nephrology providers who report this measure. The commenter urged CMS to consider creating a denominator exclusion for measure Q130 (CMS 68v10) for patients who are undergoing dialysis, OR remove the current dialysis SNOMED code from the measure's value set.

The 2020 eCQM Specification for this measure states that the initial population for this measure includes "All visits occurring during the 12-month measurement period for patients aged 18 years and older" *(a)*. Additionally, the "Encounter to Document Medications" Value Set currently included in the measure includes SNOMED code 385973000 - Dialysis care management (procedure). The consequence of using this SNOMED code is that any patients who are undergoing dialysis are eligible for the measure each time they have a Dialysis visit. Clinically, dialysis patients have eligible encounters multiple times a week and it is unnecessary to reconcile a dialysis patient's medication mere days after their previous encounter, as no significant changes are likely to have occurred. The frequency that providers are required to reconcile medications discourages Nephrology TIN's from using this measure.

Category	Description
Response: As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years. Part of the Meaningful Measures Initiative is to align with current medical guidelines and implementing measures the drive quality care, reduce risk factors, and promote positive patient outcomes. After consideration of public comments, we are finalizing the changes to measure Q130 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.26 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0418 / 0418e
Quality#:	134
CMS eCQM ID:	CMS2v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications. **The description is revised to read: For all collection types:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **The definition is revised to read: For all collection types:** Screening: Completion of a clinical or diagnostic tool used to identify people at risk of developing or having a certain disease or condition, even in the absence of symptoms. Standardized Depression Screening Tool: A normalized and validated depression screening tool developed for the patient population in which it is being utilized Examples of standardized depression screening tools include but are not limited to: * Adolescent Screening Tools (12-17 years) * Patient Health Questionnaire for Adolescents (PHQ-A) * Beck Depression Inventory-Primary Care Version (BDI-PC) * Mood Feeling Questionnaire (MFQ) * Center for Epidemiologic Studies Depression Scale (CES-D) * Patient Health Questionnaire (PHQ-9) * Pediatric Symptom Checklist (PSC-17) * PRIME MD-PHQ2 * Adult Screening Tools (18 years and older) * Patient Health Questionnaire (PHQ9) * Beck Depression Inventory (BDI or BDI-II) * Center for Epidemiologic Studies Depression Scale (CES-D) * Depression Scale (DEPS) * Duke Anxiety-Depression Scale (DADS) * Geriatric Depression Scale (GDS) * Cornell Scale for Depression in Dementia (CSDD) * PRIME MD-PHQ2 * Hamilton Rating Scale for Depression (HAM-D) * Quick Inventory of Depressive Symptomatology Self-Report (QID-SR) * Computerized Adaptive Testing Depression Inventory (CAT-DI) * Computerized Adaptive Diagnostic Screener (CAD-MDD) * Perinatal Screening Tools * Edinburgh Postnatal Depression Scale * Postpartum Depression Screening Scale * Patient Health Questionnaire 9 (PHQ-9) * Beck Depression Inventory * Beck Depression Inventory-II * Center for Epidemiologic Studies Depression Scale * Zung Self-rating Depression Scale Follow-Up Plan: Documented follow-up for a positive depression screening must include one or more of the following: * Referral to a practitioner who is qualified to diagnose and treat depression * Pharmacological interventions * Other interventions or follow-up for the diagnosis or treatment of depression **The numerator definition is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Examples of a follow-up plan include but are not limited to: • Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression • Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Patients with a Documented Reason for not Screening for Depression (Denominator Exception) Patient Reason(s) Patient refuses to participate OR Medical Reason(s)

Category	Description
	Documentation of medical reason for not screening patient for depression (e.g., cognitive, functional, or motivational limitations that may impact accuracy of results; patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status) **Updated denominator exclusion definition: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Revised: Not Eligible for Depression Screening or Follow-Up Plan (Denominator Exclusion) Patients who have been diagnosed with bipolar disorder- F31.10, F31.11, F31.12, F31.13, F31.2, F31.30, F31.31, F31.32, F31.4, F31.5, F31.60, F31.61, F31.62, F31.63, F31.64, F31.70, F31.71, F31.72, F31.73, F31.74, F31.75, F31.76, F31.77, F31.78, F31.81, F31.89, F31.9 Patients who have been diagnosed with depression-- F01.51, F32.0, F32.1, F32.2, F32.3, F32.4, F32.5, F32.89, F32.9, F33.0, F33.1, F33.2, F33.3, F33.40, F33.41, F33.42, F33.8, F33.9, F34.1, F34.81, F34.89, F43.21, F43.23, F53.0, F53.1, O90.6, O99.340, O99.341, O99.342, O99.343, O99.345 **The guidance is revised to read: For the eCQM Specifications collection type:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. This eCQM is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. Screening Tools: * An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. * The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record * The depression screening must be reviewed and addressed in the office of the provider, filing the code, on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice * The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter * The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool Follow-Up Plan: The follow-up plan must be related to a positive depression screening, for example: "Patient referred for psychiatric evaluation due to positive depression screening." Examples of a follow-up plan include but are not limited to: * Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression * Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool will not qualify as a follow-up plan. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator criteria: For the Medicare Part B Claims Measures Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients aged ≥ 12 years. **For the eCQM Specifications collection type:** Added physical therapy MIPS eligible clinician. **Updated denominator note: For the Medicare Part B Claims Measures Specifications and the MIPS CQMs Specifications collection types:** Added: The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. **Updated denominator exclusion:** **For the eCQM Specifications collection type:** Revised: Patients who have been diagnosed with depression or with bipolar disorder. **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Revised: Documentation stating the patient has had a diagnosis of depression or has had a diagnosis of bipolar disorder. **Updated numerator: For the eCQM Specifications collection type:** Removed additional evaluation or assessment for depression and suicide risk assessment as follow-up from the measure in header and from technical specifications and add guidance statement regarding suicide risk assessment. **The numerator instruction is revised to read: For the Medicare Part B Claims Measures Specifications collection type and the MIPS CQM Specifications collection type:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. Depression screening is required once per measurement period, not at all encounters. An age-appropriate, standardized, and validated depression screening tool must be

Category	Description
	used for numerator compliance. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. The depression screening must be reviewed and addressed in the office of the provider on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool, will not qualify as a follow-up plan.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the description to provide clarity and better align with the measure intent. We proposed to update the measure language in the definitions, guidance, and numerator note sections to provide clarity as to what constitutes a follow-up plan. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, since that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Additionally, suicide risk assessments have been removed as a numerator compliant follow-up plan option as this should be completed when appropriate and based on the assessment by the clinician regarding the severity of the patient's symptoms of depression at the time of depression screening. We also proposed to update the measure language and denominator exclusions to reflect that this measure is screening of depression for patients who have not been previously diagnosed or have an active diagnosis of depression or bipolar disorder. This preventive measure assesses screening and follow up plan for patients that are screened positive for depression. We also proposed to update the denominator criteria for the Medicare Part B Claims Measure Specifications and the MIPS CQM Specifications collection types to align with the measure denominator language which states patients age 12 or older at the beginning of the measurement period. Additionally, we proposed to add the physical therapy MIPS eligible clinician type based on stakeholder feedback regarding the applicability of this measure to this clinician type. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

We proposed a substantive change to the numerator instruction for the Medicare Part B Claims Measures Specifications collection type and the MIPS CQM Specifications collection type; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:

A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. Depression screening is required once per measurement period, not at all encounters. An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. The depression screening must be reviewed and addressed in the office of the provider on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter.

The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. In order to satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool.

Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool, will not qualify as a follow-up plan.

This additional refinement of adding 'In order' prior to 'to satisfy' does not affect the intent of the proposed substantive change.

Comment: One commenter cited follow-up plan may not follow provider workflow. For example, an EHR software may capture the date the order was signed which may be signed by the provider the next day (not the day of the order). The commenter recommended that grace period be allowed for providers to get caught up with paper work (1 to 3 days after the encounter).

Response: We thank the commenter for their comment. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years.

Comment: One commenter agreed with the proposal to remove suicide risk assessment from a numerator option. A suicide risk assessment is a screening tool, and if needed, should be done at the initial screening point, rather than a follow up.

Response: We thank the commenter for supporting the change to this measure.

After consideration of public comments, we are finalizing the changes to measure Q134 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR

Category	Description
50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Measure Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Measure Specifications. For this measure, we note that 2020 CMS Web Interface Measure Specifications included the following change, Numerator/Numerator Codes/Numerator Drug Codes: Follow-up Plan (For Positive Screen) REMOVED ADDITIONAL_EVAL_CODE SNM. Such change is applicable for the 2021 MIPS performance period/2023 MIPS payment year given that the 2021 CMS Web Interface Measure Specifications reflect the 2020 CMS Web Interface Measure Specifications. Also, it should be noted that the CMS Web Interface Specifications collection type is not able to establish a benchmark for this measure. Thus, this measure will be excluded from the Merit-based Incentive Payment System (MIPS) scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the measure meets the data completeness requirement and the data applicable to the measure is reported via the CMS Web Interface Measure Specifications.	

D.27 Melanoma: Continuity of Care – Recall System

Category	Description
NQF # / eCQM NQF #:	N/A/N/A
Quality#:	137
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q137. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q137 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.28 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care

Category	Description
NQF # / eCQM NQF #:	0563 / N/A
Quality#:	141
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications as it shows very high performance year after year leaving little opportunity to drive improvement in quality outcomes. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.

Comment: One commenter opposed CMS's proposal to remove the claims collection type from measure Q141. Removal of the measure from claims would adversely impact ophthalmologists, particularly those in small and rural practices who must rely on the claims reporting collection type because they cannot afford to adopt CEHRT. The commenter recognized that this measure is topped out under the claims collection type, but clinicians reporting these measures are already limited in the number of points they can receive for this measure.

Response: We understand that ensuring there are measures available for small and rural practices is important; however, we strive to ensure that all measures align with the Meaningful Measures Initiative. After careful considerations, we will maintain the Medicare Part B Claims Measure Specifications collection type for consistency and stability as it is not extremely topped out and still in alignment with guidelines, but may consider removal in the future.

After consideration of public comments, we are not finalizing the changes to measure Q141 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.29 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v9
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated logic**: **For the eCQM Specifications collection type:** Revised logic to limit the date range for chemotherapy administered within 31 days before and after the measurement period. Added definition: Chemotherapy within 30 days Prior and After the Measurement Period. **The guidance is revised to read: For the eCQM Specifications collection type:** This eCQM is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face interaction. Due to the nature of some applicable coding related to radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face encounter occurring on the actual billing date or within the 6 days prior to the billing date. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy within 30 days prior to the encounter AND administered chemotherapy within 30 days after the date of the encounter. Pain intensity should be quantified using a standard instrument, such as a 0-10 numerical rating scale, visual analog scale, a categorical scale, or pictorial scale. Examples include the Faces Pain Rating Scale and the Brief Pain Inventory (BPI). This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated Instructions: For the MIPS CQM Specifications collection type:** Revised note to reflect both face-to-face and telehealth encounters are allowed. **The denominator note is revised to read: For the MIPS CQMs Specifications collection type:** For the reporting purposes for this measure, in instances where CPT code 77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face or telehealth encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face or telehealth encounter occurring on the actual billing date or within the 6 days prior to the billing date. **Updated denominator: For all collection types:** Added telehealth as eligible encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the logic within the eCQM Specifications collection type to limit the range of time for chemotherapy procedures to only capture the chemotherapy procedures that satisfy the measure requirements. This will decrease implementation burden for some MIPS eligible clinicians while improving reporting capabilities for some practices. Additionally, the eCQM Specifications and MIPS CQMs Specifications collection types the guidance/denominator note was proposed to be revised to allow for a lookback period when utilizing CPT codes that may not have the same billing and encounter date. This will align more closely with actual clinical workflow and encounter billing practices. We proposed to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter indicated that the rationale included in the 2021 PFS proposed rule for Table D.29 should be corrected to read: "We propose to add telehealth encounters as denominator eligible for submission criteria 1 and 2 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured." Another commenter supported the addition of telehealth reporting for this measure.

Response: We thank the commenter for their comment regarding telehealth for measure Q143. As currently specified for PY 2020, the measure allows for telehealth visits for denominator submission criteria two, but contains a telehealth exclusion for denominator submission criteria one. For PY2021, we proposed to allow for telehealth as an eligible encounter for submission criteria one so both submission criteria will allow for telehealth encounters to ensure a complete patient population is captured for assessment of the quality action.

Comment: One commenter supported the proposed changes to measure Q143, which ensure pain assessment and subsequent management is incorporated into virtual health care and align with current cancer care guidelines. It is critical to account for the growing need and utilization of virtual care, and the variety providers qualified to conduct these visits, including advanced practice providers.

Category	Description
Response: We thank the commenter for supporting the changes to this measure. After consideration of public comments, we are finalizing the changes to measure Q143 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.30 Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
NQF # / eCQM NQF #:	0383 / N/A
Quality#:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Substantive Change:	**Updated instructions:** Added: THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1) All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain OR 2) All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **The denominator is revised to read:** Submission Criteria 1: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who reporting having pain Denominator (Submission Criteria 1): All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain Submission Criteria 2: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain Denominator (Submission Criteria 2): All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **Updated denominator: For all collection types:** Added telehealth as eligible encounter. **Updated denominator criteria:** Revised: Submission Criteria One • Removed coding for radiation therapy Submission Criteria Two • Added coding for cancer diagnosis • Added coding for patient procedure **Updated denominator note: For Submission Criteria Two:** Added: For the reporting purposes of this measure, in instances where CPT code77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments. **The numerator is revised to read:** NUMERATOR (SUBMISSION CRITERIA 1): Patient visits that included a documented plan of care to address pain. NUMERATOR (SUBMISSION CRITERIA 2): Patient visits that included a documented plan of care to address pain. **Updated numerator instructions: For Submission Criteria Two:** Added: A documented plan of care may include: use of opioids, nonopioid analgesics, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval. **Updated numerator options: For Submission Criteria Two:** Added: **Performance Met:** Plan of care to address pain documented **Performance Not Met:** Plan of care for pain not documented, reason not otherwise specified
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to separate the measure into two submission criteria based upon treatment to add clarity based on stakeholder feedback. This also aligns the measure with the format of measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. The patient procedure coding was updated to ensure only coding applicable to the updated submission criteria is included within the denominator criteria. We proposed to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

We proposed a substantive change to the denominator note for submission criteria two; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
For the reporting purposes of this measure, in instances where CPT code77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments.

This additional refinement of the addition of 'or telehealth' in the final sentence does not affect the intent of the proposed substantive change, but clarifies and aligns with the other revisions.

Comment: One commenter indicated that the rationale included in the 2021 PFS proposed rule for Table D.30 should be corrected to read: "We propose to add

Category	Description
telehealth encounters as denominator eligible for submission criteria 1 and 2 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured." Another commenter supported telehealth reporting for this measure. **Response:** We thank the commenter for their comment regarding telehealth for measure Q144. As currently specified for PY 2020, the measure allows for telehealth visits for all procedural codes, but contains a telehealth exclusion for patient encounters associated with the chemotherapy patient population. For PY2021, we proposed to allow for telehealth as an eligible encounter for submission criteria one, which is those patients who are receiving chemotherapy and the only criteria for a patient encounter, so both submission criteria will allow for any available telehealth encounters and procedures, to ensure a complete patient population is captured for assessment of the quality action. **Comment**: One commenter supported the proposed changes to measure Q144, which ensures pain assessment and subsequent management is incorporated into virtual health care and align with current cancer care guidelines. It is critical to account for the growing need and utilization of virtual care, and the variety of providers qualified to conduct these visits, including advanced practice providers. **Response:** We thank the commenter for supporting the changes to this measure. After consideration of public comments, we are finalizing the changes to measure Q144 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.31 Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	145
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).
Substantive Change:	**Updated numerator instructions: For all collection types:** Added: Documentation: Information populating the final report may reside in a dedicated field in the electronic health record (EHR) or picture archiving and communication system (PACS), however fluoroscopy exposure dose or time should be included in the final report to be readily accessible in all circumstances.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria encounter coding to ensure that all of the codes are associated with fluoroscopy and to create a more complete patient population. Additionally, we proposed to add numerator instructions to further clarify how the fluoroscopy information should be recorded in the final report to be numerator compliant and meet the intent of the measure.

We proposed a substantive change to the numerator instructions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation: Information populating the final report may reside in a dedicated field in the electronic health record (EHR) or picture archiving and communication system (PACS), however fluoroscopy exposure dose or time should be included in the final report in order to be readily accessible in all circumstances. This additional refinement does not affect the intent of the proposed substantive change.

Comment: One commenter recognized the changes to measure Q145 without issue. A second commenter supported the changes as they better fit the intent of the measure and will lessen clinical burden to some extent.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q145 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.32 Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	147
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.
Substantive Change:	**The denominator is revised to read: For all collection types:** All final reports for patients, regardless of age, undergoing bone planar and whole body scintigraphy.
Steward:	Society of Nuclear Medicine and Molecular Imaging
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator to account for encounter codes that can be utilized for imaging other than bone scintigraphy. This will narrow the eligible patient population to those using bone imaging agents and only assess MIPS eligible clinicians that are relevant to this measure's intent.

Comment: One commenter supported the changes to measure Q147 as they better fit the intent of this measure and will lessen clinical burden to some extent.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q147 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.33 Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).
Substantive Change:	**The title is revised from 'Rheumatoid Arthritis (RA): Tuberculosis Screening' to:** Tuberculosis Screening Prior to First Course Biologic Therapy **The description is revised to read:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period. **The instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for patients who are being considered or prescribed a first course of biologic disease-modifying anti-rheumatic drug therapy seen during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The denominator is revised to read:** All patients aged 18 years and older who are receiving a first course of therapy using a biologic DMARD. **The denominator instructions are updated to read:** Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and were not prescribed DMARD biologic therapy in the 12 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes:-Abatacept (Orencia) -Adalimumab (HUMIRA) -Anakinra (Kineret) -Baricitinib (Olumiant) -Canakinumab (ILARIS) -Certolizumab pegol and lyophilized certolizumab pegol (CIMZIA) -Denosumab (Prolia) -Etanercept (Enbrel) -Golimumab (Simponi) -Infliximab (REMICADE) -Infliximab-dyyb (Inflectra) -Infliximab-abda (Renflexis) -Sarilumab (KEVZARA) -Secukinumab (Cosentyx) -Tocilizumab (ACTEMRA) -Tofacitinib (XELJANZ) -Ustekinumab (STELARA) The list of biologic DMARD therapies is subject to change as new therapies are approved by the FDA. **Updated denominator criteria:** Removed: 'Diagnosis for RA' criteria Revised**:** Patient receiving first-time biologic disease modifying anti-rheumatic drug therapy **Updated denominator:** Added telehealth as eligible encounter. **The numerator is revised to read:** Patients for whom any record of TB testing is documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic prescription. **Updated numerator definition:** Removed 'Biologic DMARD Therapy' definition. **Updated numerator options:** Revised: **Performance Met:** TB screening performed and results interpreted within 12 months prior to initiation of first-time biologic disease modifying anti-rheumatic drug therapy.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to expand the measure to remove disease specificity from the measure to assess all patients prescribed a first course biologic DMARD therapy. This will expand monitoring of patient safety guidance compliance to all patients initiating DMARD therapy. The language throughout the measure has been updated to align with the change in patient population. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

We proposed a substantive change to the denominator instructions; however, during review of this proposed substantive change, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and were not prescribed DMARD biologic therapy in the 12 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes:-Abatacept (Orencia) -Adalimumab (HUMIRA) -Anakinra (Kineret) -Baricitinib (Olumiant) -Canakinumab (ILARIS) -Certolizumab pegol and lyophilized certolizumab pegol (CIMZIA) -Etanercept (Enbrel) -Golimumab (Simponi) -Infliximab (REMICADE) -Infliximab-dyyb (Inflectra) -Infliximab-abda (Renflexis) -Sarilumab (KEVZARA) -Secukinumab (Cosentyx) -Tocilizumab (ACTEMRA) -Tofacitinib (XELJANZ) -Ustekinumab (STELARA) The list of biologic DMARD therapies is subject to change as new therapies are approved by the FDA.
This refinement removes the medication Denosumab (Prolia) from the list of biological DMARD therapies as it is not necessary to complete a TB test prior to use of this medication. Inclusion of this medication would be in contradiction of current medical guidelines and would subject patients to unnecessary testing, with potential of deleterious effects, while creating additional and unnecessary costs. It is for these reasons that we feel Denosumab (Prolia) must be removed as patient safety and making care affordable are healthcare priorities.

Comment: One commenter supported the addition of telehealth reporting for measure Q176.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

Category	Description
Comment: Several commenters opposed the removal of measure Q337: Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier as stated under Table C.6. The proposed update to measure Q176 would mean the denominator population would overlap with measure Q337. Instead of the measure being specific to rheumatoid arthritis (measure Q176) or psoriasis patients (measure Q337), it looks to assess all patients prescribed a first course biologic DMARD therapy. The commenters stated that the revision to measure Q176 does not sufficiently cover the patients that dermatologist treat or the medications that are used, as are currently reported under measure Q337. **Response:** After consideration of public comments, we are no longer finalizing the removal of measure Q337. See Table C.6 of the final rule for further information. We encourage the commenters to reach out to the measure steward to work towards possible revisions in an effort to develop a unified measure reflecting a broader patient population and more inclusive medication therapy for possible future implementation. After consideration of public comments, we are finalizing the changes to measure Q176 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.34 Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	178
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: Several commenter supported the addition of telehealth reporting for measure Q178. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q178 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.35 Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	180
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q180.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q180 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.36 Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	181
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**Updated denominator: For all collection types:** Added care management services.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add coding applicable to chronic care management services as these capture encounters where screening may occur and is an appropriate patient population for this measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q181 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.37 Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**Updated denominator: For all collection types:** Added home health and domiciliary/rest home settings. **The numerator note is revised to read: For all collection types**: The intent of this measure is for a functional outcome assessment tool to be utilized at a minimum of every 30 days but submission is only required at each qualifying encounter due to coding limitations. Therefore, for visits occurring within 30 days of a previously documented functional outcome assessment, the numerator quality-data code G8942 should be used for submission purposes. **Updated numerator definition: For all collection types**: Revised: Current (Functional Outcome Assessment) – A patient having a documented functional outcome assessment utilizing a standardized tool and a care plan if indicated at a qualifying encounter within the previous 30 days.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add the home health and domiciliary/rest home settings as denominator eligible settings as functional assessments may occur at these visits and would lead to a more complete denominator eligible patient population. Additionally, we proposed to update the definition for 'Current (Functional Outcome Assessment)' and the numerator note to clarify the measure intent, which is to only report for qualifying encounters and not each visit.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q182 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.38 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Added data element: "Best Corrected Visual Acuity Exam Using Snellen Chart" (2.16.840.1.113883.3.526.3.1560)
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	For the eCQM Specifications collection type, we proposed to add a data element for "Best Corrected Visual Acuity Exam Using Snellin Chart" allowing an alternative method to capture an exam commonly used in clinical practice that may not have been accurately captured prior. This added numerator compliant option is clinically in line with the measure intent and appropriate for inclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q191 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.39 Radiology: Stenosis Measurement in Carotid Imaging Reports

Category	Description
NQF # / eCQM NQF #:	0507 / N/A
Quality#:	195
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.
Substantive Change:	**The instructions are revised to read: For all collection types:** This measure is to be submitted each time a carotid imaging study is performed during the performance period for patients aged 18 years and older during the submission period. There is no diagnosis associated with this measure. Merit-based Incentive Payment System (MIPS) eligible clinicians who provide the professional component of diagnostic imaging studies of the carotids will submit this measure. **The denominator is revised to read: For all collection types**: All final reports for carotid imaging studies (neck MR angiography [MRA], neck CT angiography [CTA], neck duplex ultrasound, carotid angiogram) performed on patients aged 18 years and older during the submission period. **Updated denominator criteria: For all collection types:** Added: Patients aged ≥ 18 years on date of encounter.
Steward:	American College of Radiology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure's eligible patient population to include only patients aged 18 years and older. This will allow for closer monitoring regarding who is eligible and more appropriate for inclusion in the eligible patient population, which will decrease overall burden for the clinicians reporting this measure.

Comment: One commenter recognized the changes to measure Q195 without issue. A second commenter supported the changes to this measure as they better fit the intent of this measure and will lessen clinical burden to some extent.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q195 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.40 Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the knee impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near Discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Knee FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We proposed to update the denominator exception language to add clarity and better align with measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q217 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.41 Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the hip impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Hip FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We proposed to update the denominator exception language to add clarity and better align with measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q218 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.42 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator criteria:** Revised ICD-10 coding for 'With a lower leg, foot, or ankle impairment and/or diagnosis pertaining to a functional deficit affecting lower leg, foot, or ankle'. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the lower leg, foot or ankle impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Hip FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We proposed to update the denominator exception language to add clarity and better align with measure's intent. Additionally, we proposed to update the ICD-10 coding related to the denominator criteria statement, 'With a lower leg, foot, or ankle impairment and/or diagnosis pertaining to a functional deficit affecting lower leg, foot, or ankle,' to align with current coding.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q219 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.43 Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to refine the description for easier readability. We proposed to update the denominator exception language to add clarity and better align and communicate the measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q220 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.44 Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to refine the description for easier readability. We proposed to update the denominator exception language to add clarity and better align and communicate the measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q221 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.45 Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to refine the description for easier readability. We proposed to update the denominator exception language to add clarity and better align and communicate the measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q222 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.46 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications. **The description is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. **The description is revised to read: For the eCQM Specifications collection type**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user **Updated instructions: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised the language to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated guidance: For the eCQM Specifications collection type:** Revised**:** To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the 12-month period. If a patient has multiple tobacco use screenings during the 12-month period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. Added: To promote a team-based approach to patient care, the tobacco cessation intervention can be performed by another healthcare provider; therefore, the tobacco use screening and tobacco cessation intervention do not need to be performed by the same provider or clinician. **Updated denominator: For all collection types:** Added Physical Therapy MIPS eligible clinician and telehealth as eligible encounters for all submission criteria. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Updated logic: For the eCQM Specifications collection type:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated numerator: For the eCQM Specifications collection type:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. Additionally, revised the logic to unlink the intervention from having to occur after the tobacco user status. **Updated numerator: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure to shorten the look back period to 12 months and require that tobacco screening and cessation, if patient screened positive, occur every 12 months. The revision is based upon stakeholder feedback, input from the eCQM clinical review process, and the measure steward's technical expert panel (TEP). We agreed that it is important to do this annually as tobacco use is an important population health concern and smoking is the leading cause of preventable death (https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm). The language throughout the measure specification is being

Category	Description
	revised to reflect this update. Additionally, we proposed to add physical therapy MIPS eligible clinicians to the denominator eligible encounters as this is applicable to their scope of practice. For the eCQM Specifications collection type we proposed to unlink the intervention from having to occur after the tobacco status within the measure logic. This revision is better aligned with the clinical reality that for patients actively trying to quit a plan will be in place and further tobacco cessation intervention is redundant, as well as lessening the burden of clinicians, especially for those patients who are not planning on quitting. The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agreed that this guidance update is clinically appropriate and aligns better with clinical care workflows. Additionally, we proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

Comment: One commenter supported the update of the denominator to add physical therapy MIPS-eligible clinicians and telehealth as eligible encounters for measure Q226. Multiple commenters supported the addition of telehealth reporting for this measure.

Response: We thank the commenters for supporting adding physical therapists to this measure and for supporting the adding telehealth as eligible encounters.

Comment: One commenter greatly appreciated the numerator change to tobacco cessation for eCQMs, specifically the language "Additionally, revised the logic to unlink the intervention from having to occur after the tobacco user status."

Response: We thank the commenter for supporting this change to the numerator language for eCQMs.

Comment: One commenter agreed, and one commenter disagreed with the proposal to shorten the lookback period for evidence of tobacco use screening from 24 to 12 months. The vast majority of smokers pick up the habit before age 18. Consequently, while tobacco screening and intervention should – of necessity – be more frequent in the years of patient adolescence and young adulthood, there is little evidence to indicate more frequent screening is warranted in older adults. The commenter preferred that the lookback period stay at 24 months. An alternative – though admittedly a burdensome one – is for the lookback period to vary by age to account for clinical realities.

Response: We thank the commenters for their comments. The U.S. Preventive Services Task Force indicated that "Tobacco use is the leading preventable cause of disease, disability, and death in the United States. Cigarette smoking results in more than 480,000 premature deaths each year and accounts for approximately 1 in every 5 deaths". Due to the harmful effect tobacco use can have on patients' health, we believe that clinicians should engage with their patients to screen for tobacco use and, if positive, provide tobacco cessation counseling annually.

After consideration of public comments, we are finalizing the changes to measure Q226 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications. In addition, we are not finalizing the proposed additional telehealth encounter eligibility substantive change for the eCQM Specifications collection type because this is already specified in the current measure.

D.47 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specification and MIPS CQMs Specifications **Updated denominator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: The diagnosis of essential hypertension must be present sometime between 1 year prior to the measurement period and before the end of the measurement period (January 1, 2020 through December 31, 2021). **Updated denominator exclusion: For the eCQM Specification collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specification collection type:** Added coding to identify patients with advanced illness and frailty **Updated logic: For the eCQM Specifications collection type:** Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to and during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: 1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. 2. Patients 66-80 years of age with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period 3. Patients 66-80 years of age with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period Added: 1. Patients 81 years of age and older with at least one claim/encounter for frailty during the measurement period. **Updated instructions note/numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: • Reported by or taken by the patient (with the exception of BP values taken by a remote monitoring device, which are then reported to the provider).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed that the denominator exclusion language and logic be updated in all collection types to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection type we proposed to update the logic to allow for new hypertension diagnoses within the first 6 months of the performance period to better align with the intent of the measure. We proposed to add a denominator note to clarify the patient population eligible for the measure and to reflect the revision in timing for the essential hypertension diagnosis; ensuring patients that should be assessed are included within the denominator eligible patient population. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We also proposed to update the instructions note and the numerator note to add clarity regarding the use of remote monitoring devices for the purposes of this measure in response to stakeholder feedback. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.
Comment: One commenter stated that although telehealth is available for this measure, it is restricted to using only remote devices (via Bluetooth technology). The concern is that this may be restrictive to some patients who might benefit from telehealth (virtual visits) but do not have and/or cannot afford a new device and/or technology. The commenter recommended that the measure follow HEDIS specifications that allows visual confirmation on the blood pressure measuring device by the provider during the virtual visit and then to record the blood pressure in the EHR.	

Category	Description
	Response: We thank the commenter for their comment. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years. After consideration of public comments, we are finalizing the changes to measure Q236 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications. We have identified a technical error in the language for the update to the eCQM Specifications collection type for the denominator logic. For the eCQM Specifications collection type, we inadvertently indicated that the timeframe for the hypertension diagnosis must be present prior to "and" during the measurement period. To resolve this technical error, the "and" was replaced with "or". We have updated the language for the logic from the proposed change for the eCQM Specifications collection type as follows: **Technical error:** Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to and during the measurement period. **To resolve technical error**: Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to OR during the measurement period. This reflects the change to the denominator logic proposed for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. The 2021 performance period eCQM measure specifications have been published since May 7, 2020 on the CMS Electronic Clinical Quality Improvement (eCQI) Resource Center website at https://ecqi.healthit.gov/ecqm/ep/2021/cms165v9 and we have not received feedback or public comments regarding this change in denominator logic. Further refinements were made to the measure specifications in order to align with the proposed update to the denominator note for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. We are finalizing a modification of the Measure Description for the Medicare Part B Claims Measure Specifications, eCQM Specification, and MIPS CQMs Specifications collection types as follows: **Current:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. **Revised to read:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. Additionally, we are finalizing a modification to the Denominator Statement for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types, and the Initial Patient Population for the eCQM Specifications collection type. The following finalized modification pertains to the Denominator Statement for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. **Current:** Patients 18-85 years of age who had a visit and a diagnosis of hypertension overlapping the measurement period. **Revised to read:** Patients 18-85 years of age who had a visit and diagnosis of essential hypertension overlapping the measurement period or the year prior to the measurement period. The following finalized modification pertains to the Initial Patient Population for the eCQM Specifications collection type. **Current:** Patients 18-85 years of age who had a visit and diagnosis of essential hypertension overlapping the measurement period. **Revised to read:** Patients 18-85 years of age who had a visit and diagnosis of essential hypertension overlapping the measurement period or the year prior to the measurement period. We are finalizing the denominator note for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types as proposed. For the reasons noted above, we are finalizing a modification of the logic for the eCQM Specifications collection type: Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to or during the measurement period. The additional changes to the description, denominator statement, and initial patient population do not affect the intent of the proposed substantive change, but adds alignment and clarity between the collection types in order to ensure proper implementation within and across collection types.

D.48 Use of High-Risk Medications in the Elderly

Category	Description
NQF # / eCQM NQF #:	0022 / N/A
Quality#:	238
CMS eCQM ID:	CMS156v9
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. 1) Percentage of patients who were ordered at least one high-risk medication. 2) Percentage of patients who were ordered at least two of the same high-risk medications.
Substantive Change:	**The title is revised from 'Use of High-Risk Medications in the Elderly' to:** Use of High-Risk Medications in Older Adults. **The description is revised to read:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications. **Updated measure analytics: For all collection types**: One performance rate. **The guidance is revised to read: For the eCQM Specifications collection type**: The intent of the measure is to assess if the patient has been prescribed at least two of the same high-risk medications on different days. The intent of the measure is to assess if the reporting provider ordered the high-risk medication(s). If the patient had a high-risk medication previously prescribed by another provider, they would not be counted towards the numerator unless the reporting provider also ordered a high-risk medication for them. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated instructions: For the MIPS CQMs Specifications collection type:** Removed language related to the submission of two performance rates and two submission criteria. **Updated denominator: For all collection types:** Removed submission criteria one. **For MIPS CQMs Specifications collection type:** Added ophthalmology, skilled nursing facility, and domiciliary/rest home settings and preventive care services. **The numerator is revised to read: For all collection type**: Patients with at least two orders for the same high-risk medication on different days during the measurement period. **Updated numerator: For the MIPS CQMs Specifications collection type:** Removed submission criteria one numerator. Revised High-Risk Medications at any dose or duration Table 1: Added: Pyrilamine, Orphenadrine, Chlordiazepoxide-clidinium, Methscopolamine, Glimepiride Removed: Clidinium Chloradiazepoxide, Ticlopidine, Pentazocine **For the eCQM Specifications collection type:** Added medication value sets: Scopolamine, Secobarbital, Propantheline, Doxylamine, Ergoloid Mesylates, Butalbital, Amobarbital, Pentobarbital
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove submission criteria one from this measure and continue to assess the percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications. This change will lessen clinician burden while still assessing an important aspect of patient safety. This patient population is a better assessment of the riskier, longer-term use and allows MIPS eligible clinicians/groups to address potentially inappropriate medication dispensing to improve quality outcomes. The eCQM Specifications collection type added medication value sets to the numerator to align with the Beers Criteria for Potentially Inappropriate Medication list, as well as to reflect expert review and stakeholder feedback. These updates ensure all high-risk medications are being assessed for numerator compliance. The MIPS CQMs Specifications collection type was revised to align medications across collection types. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q238 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.49 Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
NQF # / eCQM NQF #:	0643 / N/A
Quality#:	243
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.
Substantive Change:	**Updated denominator:** Added Skilled Nursing Facility, Domiciliary/Rest Home, Home Visit, and Outpatient Consultation settings. Added telehealth as eligible encounter.
Steward:	American Heart Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add settings, Skilled Nursing Facility, Domiciliary/Rest Home, Home Visit, and Outpatient Consultation, as denominator eligible as they are clinically relevant settings that can ensure that patients receive or continue outpatient cardiac rehabilitation to support positive outcomes in their clinical care. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: Several commenters supported the addition of telehealth reporting for measure Q243. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q243 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.50 Biopsy Follow-Up

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	265
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q265.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q265 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.51 Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	268
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **The denominator is revised to read:** All females, including all individuals of childbearing potential (12 years and older) with a diagnosis of epilepsy. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type. The limited patient population and adoption of the quality measure for this collection type does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. We proposed the denominator statement be revised to be more inclusive of the eligible patient population. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter requested the removal of Medicare Part B Claims Measure Specifications for measure Q268 through the measure review process. The commenter noted that these changes were not reflected in the 2021 PFS proposed rule and the measure specifications should be removed, as the measure steward is no longer maintaining these specifications.

Response: We did propose to modify the collection type to only include the MIPS CQMs Specifications collection type. We thank the commenter for their support in the removal of the Medicare Part B Claims Measure Specifications collection type.

Comment: One commenter supported the addition of telehealth reporting for measure Q268.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q268 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.52 Sleep Apnea: Severity Assessment at Initial Diagnosis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	277
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q277.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q277 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.53 Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	279
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q279.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q279 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.54 Dementia: Cognitive Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 2872e
Quality#:	281
CMS eCQM ID:	CMS149v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**The guidance is revised to read:** Use of a standardized tool or instrument to assess cognition other than those listed will meet numerator performance. Standardized tools can be mapped to the concept "Intervention, Performed": "Cognitive Assessment" included in the numerator logic below. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. In recognition of the growing use of integrated and team-based care, the diagnosis of dementia and the assessment of cognitive function need not be performed by the same provider or clinician. The DSM-5 has replaced the term dementia with major neurocognitive disorder and mild neurocognitive disorder. For the purposes of this measure, the terms are equivalent. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward's technical expert panel suggested adding language within the guidance statement to reflect that team-based care is appropriate for this measure. We agreed that this is an important concept and applicable to this measure, adding the language helps to clarify the measure intent.

Comment: One commenter supported the changes for measure Q281 related to dementia and associated screening assessments.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q281 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.55 Dementia: Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	282
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.
Substantive Change:	**The definition is revised to read:** Assessment of functional status - Functional status is assessed by use of a validated tool, direct assessment of the patient, or by querying a knowledgeable informant. A direct assessment of functional status includes an evaluation of the patient's ability to perform instrumental activities of daily living (IADL) and basic activities of daily living (ADL). **Updated denominator:** Added telehealth as eligible encounter. **The numerator instructions are revised to read:** To meet this measure, providers must assess BOTH IADL and ADL performance. 1. IADL Assessment (users must meet one of the two below bullets to meet IADL assessment component) • To meet the measure's IADL component using a validated tool, providers must use one of the following tools: o Lawton Instrumental Activities of Daily Living Scale o Bristol Activities of Daily Living Scale o Katz Index of Independence in Activities of Daily Living o Functional Activities Questionnaire o Functional Independence Measure Instrument • To meet the measure's IADL component using a direct assessment, providers must document 3 out of the following 5 domains. o Cleaning or hobbies o Money management, o Medication management, o Transportation, and o Cooking or communication 2. ADL Assessment (users must meet one of the two below bullets to meet ADL assessment component) • To meet the measure's ADL component using a validated tool, providers must use either: o Barthel ADL Index o Bristol Activities of Daily Living Scale • To meet the measure's ADL component using a direct assessment, providers must document 3 out of the following 7 domains. o Grooming, o Bathing, o Dressing, o Eating, o Toileting, o Gait, and o Transferring **The numerator notes is revised to read:** The 12-month look back period is defined as 12 months from the date of the denominator eligible encounter. Denominator Exception(s) are determined on the date of the denominator eligible encounter. Documentation of advanced stage dementia and caregiver knowledge is limited would meet the measure exception criteria. **The denominator exception is revised to read**: Documentation of advanced stage dementia and caregiver knowledge is limited.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed the measure definition and numerator instructions to provide clarity regarding expectations for numerator compliance. This updated language should address any stakeholder confusion for implementing the measure. The numerator note was updated to align with revised denominator exception. We proposed to update the denominator exception to reduce ambiguity regarding patient scenarios where an exception is clinically appropriate. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the changes for measure Q282 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure. Another commenter support adopting language in its guidance recognizing the growing use of integrated and team-based care in the diagnosis of dementia and the assessment of cognitive impairment and concur with CMS's continued recognition that functional status includes an evaluation of a patient's ability to perform instrumental activities of daily living (IADLs) and activities of daily living (ADLs). The commenter also applauded CMS's ongoing monitoring and measurement of the percentage of patients with dementia for whom there is documented screening because it reflects CMS's recognition of the critical importance of regular screening, assessment, and management of patients with dementia for other behavioral and psychiatric symptoms.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q282 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.56 Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	283
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.
Substantive Change:	**Updated denominator:** Added telehealth as eligible encounter. **The definition is revised to read:** Behavioral and Psychiatric Symptoms Screening - Screening is defined as using a validated instrument or directly examining the patient or knowledgeable informant to determine the presence or absence of symptoms from three domains: Activity disturbances, mood disturbances (including depression), and thought and perceptional disturbances. The following validated instruments can be used to meet the measure: • Dementia Signs and Symptoms (DSS) Scale • Neuropsychiatric Inventory (NPI) • Minimum Data Set (MDS) (suggested for nursing home only). **Updated numerator instructions:** Added: Thought and perceptual disturbances under 'Thought and perceptual disturbances'. Revised: Examples of reliable and valid instruments that can be used to assess behavioral and psychiatric symptoms are: Dementia Signs and Symptoms (DSS) Scale or Neuropsychiatric Inventory (NPI). For patients residing in nursing homes, it may be the Minimum Data Set (MDS). Other reliable and valid instruments may be used to assess individual measure components for activity disturbances, mood disturbances including depression, and thought and perceptual disturbances.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the definition to remove 'positive', as this was not appropriate or aligned with the definition for the purposes of this measure. Additionally, information regarding approved screening instruments was moved to this section as it is more appropriately in this section of the measure specification. We proposed to update the numerator instructions to add 'thought and perceptual disturbance' and provide greater clarity regarding the requirements of numerator compliance for this measure. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the changes for measure Q283 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q283 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.57 Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	286
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
Substantive Change:	**The denominator exception is revised to read**: Documentation patient unable to communicate and informant not available. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exception to better align with real-world clinical scenarios where safety screening could not be completed and therefore no mitigation recommendations could be provided. This change aids clinicians reporting the measure with an exception to excuse them from performance in a clinical situation they are unable to control. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the changes for measure Q286 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q286 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.58 Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	288
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Substantive Change:	**Updated denominator:** Added telehealth as eligible encounter. **Updated denominator exceptions:** Revised: Patient does not have a caregiver. Added: 1. Documentation caregiver is trained and certified in dementia care. 2. Patient/caregiver dyad has been referred to appropriate resources and connection to those resources is confirmed.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exception to reduce ambiguity regarding patient scenarios where an exception is clinically appropriate. Additionally, we proposed to add two denominator exceptions to further clarity clinical scenarios where it may not be appropriate to attribute the quality action to that MIPS eligible clinician. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the changes for measure Q288 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q288 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.59 Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	290
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q290. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q290 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.60 Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	291
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q291. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q291 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.61 Parkinson's Disease: Rehabilitative Therapy Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months. **Updated denominator exception**: Removed: Documentation of medical reason(s) for not discussing rehabilitative therapy options with patient (or caregiver). **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. Additionally, we proposed to remove the denominator exception, which allowed for medical reason(s) for not discussing rehabilitative therapy options. We agreed that MIPS eligible clinicians should discuss rehabilitative therapy options with all patients/caregivers as these therapies play an important role in not only improving function in the patient, but also their quality of life. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q293. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q293 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.61 Parkinson's Disease: Rehabilitative Therapy Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months. **Updated denominator exception**: Removed: Documentation of medical reason(s) for not discussing rehabilitative therapy options with patient (or caregiver). **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. Additionally, we proposed to remove the denominator exception, which allowed for medical reason(s) for not discussing rehabilitative therapy options. We agreed that MIPS eligible clinicians should discuss rehabilitative therapy options with all patients/caregivers as these therapies play an important role in not only improving function in the patient, but also their quality of life. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q293.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q293 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.63 Cervical Cancer Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	309
CMS eCQM ID:	CMS124v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.
Substantive Change:	**The description is revised to read:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years **The guidance is revised to read:** To ensure the measure is only looking for a cervical cytology test only after a woman turns 21 years of age, the youngest age in the initial population is 23. Patient self-report for procedures, as well as diagnostic studies should be recorded in 'Procedure, Performed' template or 'Diagnostic Study, Performed' template in QRDA-1. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. This eCQM is a patient-based measure. **The numerator is revised to read:** Women with one or more screenings for cervical cancer. Appropriate screenings are defined by any one of the following criteria: * Cervical cytology performed during the measurement period or the two years prior to the measurement period for women who are at least 21 years old at the time of the test * Cervical human papillomavirus (HPV) testing performed during the measurement period or the four years prior to the measurement period for women who are 30 years or older at the time of the test. **Updated logic**: Updated logic definition to use HPV only every 5 years and remove Pap test.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure to align with current clinical guidelines, which removes the Pap test requirement and allow HPV only testing every 5 years. This update is reflected in revisions to the description, guidance, numerator, and logic.

Comment: One commenter opposed the proposed changes to measure Q309, citing that the proposal was to update the measure to align with the current clinical guidelines, which removes the Pap/HPV test (co-testing) requirement and allow only HPV testing every 5 years. While this proposed change would align to the recently updated American Cancer Society (ACS) cervical cancer screening guidelines, the commenter stated the change is not consistent with the current recommendations from the American College of Obstetricians and Gynecologists (ACOG), the United States Preventive Services Task Force (USPSTF), the National Committee for Quality Assurance (NCQA), and numerous other guideline bodies or current clinical practice in the United States.

In response to the ACS guidelines, ACOG issued a statement affirming their current guidelines, which encompasses all three screening regimens (high-risk human papillomavirus testing alone, cervical cytology alone, and co-testing). In August 2018, the USPSTF recommended screening women aged 30 to 65 years, screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (contesting)3 with an "A" rating.

In addition, the NCQA HEDIS measure is also in conflict with the proposed revisions to the MIPS measure. The NCQA HEDIS measure for cervical cancer screening includes all three screening regimens (high-risk human papillomavirus testing alone, cervical cytology alone, and co-testing). Lastly, the proposed change to the MIPS quality measure eliminated the recommended option of co-testing for cervical cancer, a change that is inconsistent with current guidelines recommended by ACOG, the USPSTF and NCQA. Accordingly, the leading authorities in cervical cancer screening are on record that co-testing is a valuable cervical cancer screening test. The commenter asked for measure Q309 to be retained without any revisions. A second commenter sought clarification on whether the measure is specifically looking at HPV only testing every 5 years. The description and logic have conflicting definitions between the usage of cervical cytology and HPV testing, and solely HPV testing. A third commenter cited the proposal to change the measure description to remove "co-testing" from the criteria for HPV testing. The commenter indicated that it had affirmed its 2018 Practice Advisory, which includes all three cervical cancer screening strategies (high-risk human papillomavirus testing alone, cervical cytology alone, and co-testing). The commenter's current screening guidelines reflect a balance of benefit and potential harms and support shared decision-making between patients and their clinicians and recommended that changes to this measure not be finalized.

Response: We thank the commenters for their comments. The revisions to this measure are in alignment with the updated clinical guidelines. The guidelines for patients 30 to 65 years of age recommend that either; cervical cytology only be completed every 3 years or hrHPV testing alone every 5 years or co-testing (hrHPV + cervical cytology) every 5 years. The guidelines now allow hrHPV testing alone every 5 years as opposed to requiring that co-testing be completed every 5 years. However, if co-testing was completed every 5 years this would be numerator compliant as co-testing contains the hrHPV testing component. Conversely, if co-testing was completed every 3 years, this would also suffice for numerator compliance as the co-testing has the cervical cytology component. Therefore, the components of screening are all still included for the purposes of achieving the quality action for this measure, but the requirements have been revised to align with the updated guidelines. We encourage the commenters to reach out to the measure steward to discuss revisions in language to help clarify the numerator component for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q309 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.64 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v9
National Quality Strategy	Community/Population Health

Category	Description
Domain:	
Current Collection Type:	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.
Substantive Change:	**The description is revised to read: For all collection types:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive. **The guidance is revised to read: For the eCQM Specifications collection type**: This eCQM is an episode-based measure and should be reported at every visit for patients aged 18 years and older. This measure will be calculated based upon the clinical actions performed at every visit during the measurement period for each patient. The measure requires that blood pressure measurements (i.e., diastolic and systolic) be obtained during each visit to determine the blood pressure reading used to evaluate if an intervention is needed. Both the systolic and diastolic blood pressure measurements are required for inclusion. If there are multiple blood pressures obtained during a patient visit, only the last, or most recent, pressure measurement will be used to evaluate the measure requirements. The intent of this measure is to screen patients for high blood pressure and provide recommended follow-up as indicated. The documented follow-up plan must be related to the current blood pressure reading as indicated, example: "Patient referred to primary care provider for BP management." This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The instructions are revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs collections type:** This measure is to be submitted at each visit for patients seen during the measurement period. Merit-based Incentive Payment System (MIPS) eligible clinicians who submit the measure must perform the blood pressure screening at each patient visit by a MIPS eligible clinician and may not obtain measurements from external sources. **The initial patient population is revised to read: For the eCQM Specifications collection type:** All patient visits for patients aged 18 years and older at the beginning of the measurement period. **The denominator is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs collections type:** All patient visits for patients aged 18 years and older at the beginning of the measurement period. **The denominator exception is revised to read: For the eCQM Specifications collection type**: 1. Documentation of medical reason(s) for not screening for high blood pressure (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). 2. Documentation of patient reason(s) for not screening for blood pressure measurements or for not ordering an appropriate follow-up intervention if patient is pre-hypertensive or hypertensive (e.g., patient refuses). **Updated denominator exception logic: For the eCQM Specifications collection type:** Added: 1. Follow-up within 1 year 2. Follow-up within 4 weeks **The numerator is revised to read: For all collection types:** Patient visits where patients were screened for high blood pressure AND have a recommended follow-up plan documented, as indicated, if the blood pressure is pre-hypertensive or hypertensive. **Updated numerator definition: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients with a Documented Reason for not Screening or no Follow-Up Plan for High Blood Pressure (Denominator Exception) – • Documentation of medical reason(s) for not screening for high blood pressure (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). • Documentation of patient reason(s) for not screening for blood pressure measurements or for not ordering an appropriate follow-up intervention if patient is pre-hypertensive or hypertensive (e.g., patient refuses). **The numerator notes is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Although the recommended screening interval for a normal BP reading is every 2 years, to meet the intent of this measure, BP screening and follow-up must be performed at every patient visit. For patients with Normal blood pressure, a follow-up plan is not required (G8783). Denominator Exception(s) are determined on the date of the denominator eligible encounter. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure frequency so that the clinical quality action is occurring at all denominator eligible visits. Hypertension is a prevalent condition, and the United States Preventive Services Task Force (USPSTF) found good evidence that screening for and treatment of high blood pressure in adults substantially reduces the incidence of cardiovascular events. In alignment with this update, the measure language has been revised to reflect the change in frequency to all visits. Additionally, the eCQM Specifications collection type revised the logic to align with the measure's reporting frequency update, as well as updating the denominator exception logic to add two elements that were missing from the existing logic to ensure that all valid denominator exception options are accounted for within the logic. The denominator exception language was revised in the eCQM Specifications collection type to follow best practices and add clarity to implementing the measure. To align with this

Category	Description
	update, the definition for denominator exception was revised in the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
Comment: One commenter opposed the proposed change in the frequency of blood pressure screening required for this measure from annual to every patient encounter. CMS states that this is in response to the update on screening recommendations from the United States Preventive Services Task Force (USPSTF). The USPSTF is updating their guidance, but their most recent draft guidance states the following on recommended screening frequency: The USPSTF suggests annual screening for hypertension in adults age 40 years or older and for adults at increased risk for hypertension (such as persons with high-normal blood pressure, who are overweight or obese, or who are African American). Screening less frequently (i.e., every 3 to 5 years) is appropriate for adults ages 18 to 39 years not at increased risk for hypertension and with a prior normal blood pressure reading. CMS's proposed change is in opposition to recommended best practices and unnecessarily creates additional burden for clinicians. Meaningful measures should be based on best evidence. **Response:** While the USPSTF does give these suggestions, they also note that available evidence regarding optimal screening intervals for hypertension are limited. However, given the prevalence of the condition, as hypertension affects approximately 45% of the adult U.S. population (https://www.cdc.gov/nchs/products/databriefs/db364.htm), and is a major contributing factor to chronic conditions such as heart failure, heart attack, stroke, and chronic kidney disease, we believe it is important to screen blood pressure often to ensure the opportunity to offer a timely diagnoses. After consideration of public comments, we are finalizing the changes to measure Q317 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.65 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v9
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**Modified collection type:** eCQM Specifications **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed: Exclude patients who were non-ambulatory at some point in the measurement period.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the denominator exclusion for non-ambulatory patients to address implementation challenges as there is a lack of available documentation for a non-ambulatory status. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: One commenter supported the proposal to remove the denominator exclusion for non-ambulatory patients.

Response: We thank the commenter for supporting the change to this measure.

After consideration of public comments, we are finalizing the changes to measure Q318 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.

D.66 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525 / N/A
Quality#:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**The denominator is revised to read: For all collection types:** All patients aged 18 years and older with a diagnosis of nonvalvular AF or atrial flutter who do not have a documented CHA_2DS_2-VASc risk score of 0 or 1 for men or 0, 1, or 2 for women. **The denominator/numerator note is revised to read: For all collection types:** The intent of the denominator exclusion G9931 is to allow patients with a low risk for a thromboembolic event (i.e. a CHA_2DS_2-VASc score of 0 or 1 for men or 0, 1, or 2 for women) to be excluded from the sample. This denominator exclusion serves as documentation that a patient's risk for a thromboembolic event was appropriately assessed using the CHA_2DS_2-VASc scoring tool and that the risk was low enough to not warrant anticoagulation treatment. To exclude low risk patients, eligible clinicians must use the CHA_2DS_2-VASc assessment tool to determine a patient's risk score and must document either the numeric score (i.e. 0 or 1 for men or 0, 1, or 2 for women) or all the individual risk factors assessed to support an assessment of the CHA_2DS_2-VASc score. **Updated denominator exclusion: For all collection types:** Revised: Documentation of CHA_2DS_2-VASc risk score of 0 or 1 for men; 0, 1, or 2 for women. **Updated denominator: For all collection types:** Added telehealth as eligible encounter.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure to reflect the updated guidelines regarding when it is clinically appropriate to prescribe an oral anticoagulant for patients that are diagnosed with atrial fibrillation or atrial flutter. This update is reflected in the denominator statement, denominator note, and denominator exclusion. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q326. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q326 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.67 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	331
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenters supported the addition of telehealth as an eligible encounter to measure Q331. The commenter appreciated CMS recognizing telehealth as an appropriate modality for effective, high quality patient care.

Response: We thank the commenters for supporting the substantive change to measure Q331.

After consideration of public comments, we are finalizing the changes to measure Q331 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.68 Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	332
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenters supported the addition of telehealth as an eligible encounter to measure Q332. The commenter appreciated CMS recognizing telehealth as an appropriate modality for effective, high quality patient care.

Response: We thank the commenters for supporting the change to measure Q332.

After consideration of public comments, we are finalizing the changes to measure Q332 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.69 Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	335
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication. **Updated instructions:** Revised: This measure is to be submitted each time a procedure is performed for patients undergoing delivery by C-section, or induction of labor, at less than 39 weeks gestation during the performance period. **The denominator is revised to read:** All patients, regardless of age, who gave birth during a 12-month period delivering a live singleton at < 39 weeks of gestation completed. **The numerator is revised to read:** Patients who had elective deliveries by C-section, or early inductions of labor, without medical indication. **Updated numerator options:** Revised: **Performance Met:** Early elective delivery by C-section, or early elective induction, not performed (< 39 weeks gestation). **Performance Not Met:** Early elective delivery by C-section, or early elective induction, performed (< 39 weeks gestation).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the description and instructions to provide further clarity regarding what suffices for elective deliveries. Additionally, we proposed to move the "without medical indication" from the denominator to the numerator as the denominator should capture all patients with a single live birth at less than 39 weeks gestation. The numerator assesses whether or not there was medical indication for an early elective delivery by C-section, or early elective induction. This update will better align the language with the measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q335 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.70 Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	336
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth and who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at the postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description for clarity and readability so that it is easy to understand the measure intent.
We proposed a substantive change to the description; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. This additional refinement does not affect the intent of the proposed substantive change. We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q336 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.71 Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	364
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).
Substantive Change:	**Updated denominator note:** Added: Granulomas, hamartomas or lesions with internal fat, or other characteristically benign findings are not considered incidental findings in the context or intent of this measure. Therefore, they are not included in the measure denominator. However, generally accepted radiology practices should be followed for communication and management of these characteristically benign findings.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add language to the denominator note to add clarity as to which incidental findings are not appropriate for the purposes of this measure. Some incidental findings are widely known to be benign and would therefore not necessitate a specific documentation of a recommendation of no follow-up. This will reduce clinician burden and ensure only the appropriate patients are included in the denominator eligible population.

We proposed a substantive change to the denominator note; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Granulomas, hamartomas or lesions with internal fat, or other characteristically benign findings are not considered incidental findings in the context or intent of this measure. Therefore, they are not included in the measure denominator. However, generally accepted radiology practices should be followed with respect to communication and management of these characteristically benign findings.

Comment: One commenter recognized the changes to measure Q364 without issue. A second commenter supported the changes as they better fit the intent of these measures and will lessen clinical burden to some extent.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q364 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.72 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Modified collection type:** eCQM Specifications and MIPS CQMs Specifications **Updated guidance: For the eCQM Specifications collection type:** Added: When a baseline assessment is conducted with PHQ 9M, the follow-up assessment can use either a PHQ 9M or PHQ 9. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator: For the MIPS CQMs Specifications collection type:** Added telehealth with qualified non-physician healthcare professional. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Patients with a diagnosis of personality disorder emotionally labile.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the guidance for eCQM Specifications collection type to add clarity regarding the assessment that may be used for the follow-up assessment for the purposes of meeting performance for this measure. Additionally, we proposed to revise the denominator exclusion language for a diagnosis of personality disorder to further clarify ensuring the correct patient population is being excluded from quality action assessment. We proposed to update the denominator of the MIPS CQMs Specifications collection type to include telehealth encounters with qualified non-physician healthcare professionals as it would be appropriate to assess this patient population for numerator compliance. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q370 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Measure Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Measure Specifications. Also, it should be noted that the CMS Web Interface Specifications collection type is not able to establish a benchmark for this measure. Thus, this measure will be excluded from the Merit-based Incentive Payment System (MIPS) scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the measure meets the data completeness requirement and the data applicable to the measure is reported via the CMS Web Interface Measure Specifications.	

D.73 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v9
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Substantive Change:	**Updated logic: For the eCQM Specifications collection type:** Updated logic for 'First Referral During Measurement Period' to allow an additional, optional way to capture the first referral. **Updated denominator: For all collection types:** Added telehealth as eligible encounter. **Updated numerator: For the eCQM Specifications collection type:** Removed pathology consult note from 'Consultant Report' value set.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the logic for 'First Referral During Measurement Period' to allow for a referral order, in addition to a referral being performed. This revision is consistent with the measure intent and provides options to capture the first referral within the electronic medical record. Additionally, we proposed to remove the pathology consult note from the 'Consultant Report' value set based upon terminology updates as the availability of the general consult note is available as an option. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q374.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

Comment: One commenter requested additional clarification on the proposed updated eCQM logic to capture a referral order without a referral actually being made or conducted. It is unclear how a clinician can close the referral loop if a referral does not occur.

Response: This revision is in alignment with the intent of the measure, which is to ensure patient's referred for an outside consultation complete the encounter with a consult report being returned to the referring physician. As the measure steward, we will review and consider revision of the coding within the measure for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q374 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.74 Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	377
CMS eCQM ID:	CMS90v9
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**Updated logic**: **Initial Patient Population**: Revised timing of congestive heart failure (CHF) diagnosis in the initial population logic so it overlaps before the measurement period. **Qualifying Encounter:** Revised timing of the encounter from the start of the measurement period to the end of the measure period. **Numerator:** • Revised to ensure assessments completed during the encounter count toward the numerator. • Revised KCCQ logic to address the 6 domain subcategories used to account for the KCCQ assessment total score. • Added the KCCQ Total Assessment Score logic to include the summary score as an option to meet the KCCQ assessment requirement. • Revised timing and logic of the follow-up functional status assessment (FSA) to relate to the initial FSA performed and not the encounter. • Revised measurement period for the Veterans RAND 12 Item Health Survey (VR-12) to allow for the initial FSA to occur prior to the measurement period if the encounter occurs within the first few days of the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the initial patient population logic to ensure the CHF diagnosis occurs before the denominator eligible encounter, which aligns more closely with the measure intent. We proposed to update the qualifying encounter logic to account for leap year. This refinement will eliminate the need to adjust the number of days for leap years. Additionally, we proposed to update the numerator logic for the Kansas City Cardiomyopathy Questionnaire (KCCQ) FSA so that it can be reported by either utilizing the six domain subcategories or the total score. This added flexibility better aligns with different clinical workflows, and is consistent with measure intent. The logic and timing were revised to relate to the initial functional status (FSA) and not the encounter to better align with the measure intent. We proposed, to all the VR-12, to allow for the initial FSA to occur prior to the measurement in the instance the encounter occurs within the first few days of the measurement period to improve harmonization with the measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q377 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.75 Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The description is revised to read**: Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period. **The stratification is revised to read:** None **The initial patient population is revised to read:** Children, 6 months - 20 years of age, with a visit during the measurement period. **Updated denominator:** Removed: "Office Visit" (2.16.840.1.113883.3.464.1003.101.12.1001) "Preventive Care - Established Office Visit, 0 to 17" (2.16.840.1.113883.3.464.1003.101.12.1024) "Preventive Care Services - Established Office Visit, 18 and Up" (2.16.840.1.113883.3.464.1003.101.12.1025) "Preventive Care Services-Initial Office Visit, 18 and Up" (2.16.840.1.113883.3.464.1003.101.12.1023) "Preventive Care- Initial Office Visit, 0 to 17" (2.16.840.1.113883.3.464.1003.101.12.1022)
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to raise the minimum age for this measure to 6 months to better align with average tooth eruption. Children under 6 months of age are less likely to have teeth and would therefore not meet numerator criteria, which is why they are being removed from the initial patient population. Additionally, we proposed to update the denominator to limit the denominator eligible encounters to the "Clinical Oral Evaluation" value set as the clinical quality action is more appropriate for the dentistry MIPS eligible clinician.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q378 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.76 Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	379
CMS eCQM ID:	CMS74v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The description is revised to read**: Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period. **The stratification is revised to read:** Population 1: age 6 months-5 years Population 2: age 6-12 Population 3: age 13-20 **The initial patient population is revised to read:** Children, 6 months - 20 years of age, with a visit during the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to raise the minimum age for this measure to 6 months to better align with average tooth eruption. Children under 6 months of age are less likely to have teeth and would therefore not meet numerator criteria, which is why they are being removed from the initial patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q379 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.77 Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 1365e
Quality#:	382
CMS eCQM ID:	CMS177v9
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.
Substantive Change:	**Updated guidance:** Added: In recognition of the growing use of integrated and team-based care, the diagnosis of depression and the assessment for suicide risk need not be performed by the same provider or clinician.
Steward:	Mathematica
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agreed that this guidance update is clinically appropriate and aligns better with clinical care workflows.

Comment: One commenter stated that guidance reads "A suicide risk assessment should be performed at every visit for major depressive disorder during the measurement period." Feedback from specialists in this field voice the following: "Our concern is that therapists provide group visits and some of those teens have MDD on their problem list. Currently, suicide risk assessments are not conducted at group visits. Most patients who attend group visits also have a cadence of seeing their therapists separately." The commenter recommended that this requirement make exceptions of the required suicide assessment during group visits.

Response: We thank the commenter for their comment. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q382 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.78 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
NQF # / eCQM NQF #:	1879 / N/A
Quality#:	383
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).
Substantive Change:	**The description is revised to read:** Percentage of individuals at least 18 years of age with schizophrenia or schizoaffective disorder as of the beginning of the performance period who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period. **Updated instructions:** Revised: This measure is to be submitted a minimum of once per performance period for all patients with a preexisting (before the performance period) diagnosis of schizophrenia or schizoaffective disorder who are seen during the performance period. **The denominator statement is revised to read:** Individuals at least 18 years of age with schizophrenia or schizoaffective disorder as of the beginning of the performance period and at least two prescriptions filled for antipsychotic medications during the performance period. **Updated denominator criteria:** Revised the timing for the diagnosis for schizophrenia or schizoaffective disorder to be prior to the performance period. **Updated denominator exclusion:** Added opioid abuse with intoxication with perceptual disturbance to diagnosis for dementia. **Updated numerator note:** Revised: PDC NUMERATOR: The PDC numerator is the sum of the days covered by the days' supply of all antipsychotic prescriptions. The period covered by the PDC starts on the day within the performance period when the first prescription is filled (i.e., the index date) and lasts through the end of the performance period, or death, whichever comes first. For prescriptions with a days' supply that extends beyond the end of the performance period, count only the days for which the drug was available to the individual during the performance period. If there are prescriptions for the same drug (generic name) on the same date of service, keep the prescription with the largest days' supply. If prescriptions for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the measure language to reflect that the diagnosis of schizophrenia or schizoaffective disorder should be prior to the performance period as this aligns more closely to the intent of the measure and allows for assessment of medication adherence over a longer timeframe. We proposed to remove the "12 consecutive months" from the description as this was causing confusion amongst MIPS eligible clinicians. The denominator exclusion coding was expanded to include opioid abuse with intoxication with perceptual disturbance as this is appropriate for identifying patients with a dementia diagnosis and therefore, applicable to the denominator exclusion. Additionally, we proposed to update the numerator note to clarify that the index date is the date the prescription was first filled during the performance period.

We, as the measure steward, have decided not to finalize the substantive change to revise the timing of the diagnosis for schizophrenia or schizoaffective disorder to be prior to the performance period, to ensure patient safety and drive positive clinical outcomes. Research has shown that adherence to antipsychotic medications in individuals with first-episode psychosis (FEP) improves patient outcomes while preventing downstream harm. Treatment FEP has shown favorable outcomes, including positive effects on likelihood of remission and risk/rate of relapse, and improvement in cognitive deficits (Karson, C., et al. *Neuropsychiatric Disease and Treatment*, 12, 57-67). Given the potential long-term benefits for treatment of FEP, we believe that it is important to assess all patients with a diagnosis for schizophrenia or schizoaffective disorder for medication adherence, regardless of when diagnosed. This aligns with our healthcare priority of promoting effective treatment of chronic diseases and current clinical best practices.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q383 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years, with the exception of the revisions in the timing of diagnosis for schizophrenia or schizoaffective disorder. This revision is located within the description, instructions, denominator statement, and denominator criteria and will be updated as needed for clarity of the concept as needed within the specification.

D.79 Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	386
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q386.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q386 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.80 Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	387
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenters supported the addition of telehealth reporting for measure Q387.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q387 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.81 Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576 / N/A
Quality#:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Substantive Change:	**Updated numerator options:** Revised: Submission Criteria 1: **Performance Met:** Patient received follow-up within 30 days after discharge.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the performance met numerator option to align with the numerator statement, which prohibits the use of visits that occur on the date of discharge, as this would not meet the intent of the measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q391 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.82 Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	1407 / N/A
Quality#:	394
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.
Substantive Change:	**The description is revised to read**: The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the description to detail the components within the measure. This allows for a more clear understanding of the intent of the measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q394 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.83 Lung Cancer Reporting (Biopsy/Cytology Specimens)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	395
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.
Substantive Change:	**The numerator is revised to read: For all collection types**: Biopsy and cytology specimen reports with a diagnosis of primary non-small cell lung cancer classified into specific histologic type (including but not limited to squamous cell carcinoma, adenocarcinoma, large cell carcinoma) OR classified as NSCLC-NOS with an explanation included in the pathology report.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the numerator statement to more clearly detail the acceptable histologic types. This revision, provided based on stakeholder feedback, includes keywords that are can be used in clinical practice.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q395 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.84 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	400
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenter supported the addition of telehealth reporting for measure Q400.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q400 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.85 Appropriate Follow-up Imaging for Incidental Abdominal Lesions

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	405
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols
Substantive Change:	**The description is revised to read:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **The denominator is revised to read: For all collection types**: All final reports for imaging studies for patients aged 18 years and older with one or more of the following incidentally noted: • Cystic renal lesion that is simple appearing (Bosniak I or II) or • Adrenal lesion less than or equal to 1.0 cm or • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated denominator criteria: For all collection types:** Removed diagnostic ultrasound procedures. **The denominator note is revised to read: For all collection types:** The intent of this measure is to ensure patients with incidental findings that are highly likely to be benign do not receive follow up imaging routinely. * "Simple-appearing criteria": • § Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • § Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) When reporting this measure, masses and lesions that do not meet all the criteria for "no further work-up" as provided in Management of the Incidental Renal Mass on CT: A White Paper of the ACR Incidental Findings Committee or the Management of the Incidental Adrenal Mass on CT: A White Paper of the ACR Incidental Findings Committee should not be considered in the context or intent of this measure. However, generally accepted radiology practices should be followed for communication and management of any characteristically benign findings. A measure performance goal of 100% should not substitute for clinical judgment in individual cases. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** Removed numerator note. **Updated numerator options: For all collection types:** Revised: **Performance Not Met:** Final reports for imaging studies with follow-up imaging recommended, or final reports that do not include a specific recommendation of no follow-up.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the numerator options to add clarifying language that accounts for those instances where no follow-up recommendation is given within the final reports for imaging studies. The intent of the measure includes the documentation of follow-up recommendations within the final report. Additionally, we proposed to remove diagnostic ultrasound procedures from the denominator eligible criteria as it does not align with the intent of the measure.

We proposed a substantive change to the denominator note; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
The intent of this measure is to ensure patients with incidental findings that are highly likely to be benign do not receive follow up imaging routinely. * "Simple-appearing criteria":

- § Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017)
- § Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017)

When reporting this measure, masses and lesions that do not meet all the criteria for "no further work-up" as provided in Management of the Incidental Renal Mass on CT: A White Paper of the ACR Incidental Findings Committee or the Management of the Incidental Adrenal Mass on CT: A White Paper of the ACR Incidental Findings Committee should not be considered in the context or intent of this measure. However, generally accepted radiology practices should be followed with respect to communication and management of any characteristically benign findings. A measure performance goal of 100% should not substitute for clinical judgment in individual cases.

This additional refinement of changing 'for communication' to 'with respect to communication' does not affect the intent of the proposed substantive change.

Category	Description
Comment: One commenter supported the changes to measure Q405 as they better fit the intent of these measures and will lessen clinical burden to some extent. **Response:** We thank the commenter for supporting the changes to this measure. **Comment:** One commenter believed that the changes to measure Q405 should be more comprehensive. The measure focuses exclusively on reporting "no-follow up recommended" for incidental and likely benign renal and adrenal lesions. While the commenter understood the intention to address inappropriate use of imaging, the measure neglects appropriate usage. It should also support evidence-based recommendations for follow-up of worrisome lesions. A more balanced approach would indicate performance met when specific evidence-based guidance is used for necessary follow-up and when no follow-up is necessary, as included in the measure steward's two white papers referenced in the measure. **Response:** We encourage the commenter to reach out the measure steward to discuss possible revisions for consideration for future implementation. After consideration of public comments, we are finalizing the changes to measure Q405 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.86 Psoriasis: Clinical Response to Systemic Medications

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	410
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.
Substantive Change:	**The instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients during the performance period. The most recent denominator eligible encounter in which the numerator action was performed, should be used. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the instructions language to clarify what denominator eligible encounter should be used when assessing the quality action. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q410. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q410 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.87 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.
Substantive Change:	**Updated denominator criteria:** Diagnosis for minor blunt head trauma - removed coding for fracture of skull and facial bones and superficial injury of neck. **The definition is revised to read:** Indications for a head CT in patients presenting to the emergency department for minor blunt head trauma: Patients with no loss of consciousness (LOC) AND no post-traumatic amnesia AND any one of the following: • GCS score less than 15 • Severe headache • Vomiting • Age 65 years and older • Physical signs of a basilar skull fracture (signs include haemotympanum, "raccoon" eyes, cerebrospinal fluid leakage from the ear or nose, Battle's sign) • Focal neurological deficit • Coagulopathy • Thrombocytopenia • Currently taking any of the following anticoagulant medications**: apixaban, argatroban, betrixaban, bivalirudin, dabigatran, dalteparin, desirudin, edoxaban, enoxaparin, fondaparinux, heparin, rivaroxaban, warfarin • Dangerous mechanism of injury (i.e., ejection from a motor vehicle, a pedestrian struck, and a fall from a height of more than 3 feet or 5 stairs) OR Patients with either LOC OR Posttraumatic amnesia AND any one of the following: • GCS score less than 15 • Headache • Age 60 years and older, and less than 65 years • Drug/alcohol intoxication • Short-term memory deficits • Evidence of trauma above the clavicles (physical location, any trauma to the head or neck [i.e., laceration, abrasion, bruising, ecchymosis, hematoma, swelling, fracture]) • Posttraumatic seizure.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to update the coding for 'Diagnosis of minor blunt head trauma' base on the measure steward's clinical expert input as closed fractures of the skull and facial bones, as well as concepts that relate to neck of below the head anatomical locations. The measures intent is to capture those patients with minor blunt head trauma and the fractures captured above are not clinically appropriate for the denominator criteria and should not be assessed for the purposes of this measure. We proposed revisions to the definition language to improve clarity regarding indications for a head CT for the purposes of this measure. We agreed that these revisions better define how to determine appropriate indication(s) for a head CT.

Comment: One commenter supported the substantive changes to measure Q415, which will improve clarity regarding indications for a head CT for the purposes of this measure.

Response: We thank the commenter for supporting the changes to measure Q415.

After consideration of publication comments, we are finalizing the changes to measure Q415 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.88 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Updated denominator criteria:** Diagnosis for minor blunt head trauma - removed coding for fracture of skull and facial bones and superficial injury of neck. **The numerator definition is revised to read: For all collection types:** Low Risk for Traumatic Brain Injury according to PECARN prediction rules – Patients can be classified as low risk if ALL of the following are met: • No signs of altered mental status (e.g., agitation, somnolence, repetitive questioning, slow response to verbal communication) OR no GCS < 15 • No signs of basilar skull fracture (signs include haemotympanum, "raccoon" eyes, cerebrospinal fluid leakage from the ear or nose, Battle's sign) • No loss of consciousness • No vomiting • No severe mechanism of injury (i.e., motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorized vehicle; falls of more than 5 feet; or head struck by a high-impact object) • No severe headache.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to update the coding for 'Diagnosis of minor blunt head trauma' base on the measure steward's clinical expert input as closed fractures of the skull and facial bones, as well as concepts that relate to neck of below the head anatomical locations. The measures intent is to capture those patients with minor blunt head trauma and the fractures captured above are not clinically appropriate for the denominator criteria and should not be assessed for the purposes of this measure. We proposed revisions to the definition language to improve clarity regarding low risk for traumatic brain injury (TBI) for the purposes of this measure. We agreed that these revisions better define how to appropriately determine whether the patient is low risk for traumatic brain injury or not.

Comment: One commenter supported the substantive changes to measure Q416, which will improve clarity regarding indications for a head CT for the purposes of this measure.

Response: We thank the commenter for supporting the changes to measure Q416.

After consideration of public comments, we are finalizing the changes to measure Q416 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.89 Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053 / N/A
Quality#:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator criteria: For all collection types**: Option 1: Added denominator eligible patient encounters including discharge, outpatient observation, outpatient consultation, emergency department, home services, preventive medicine and counseling, work related/medical disability, care planning, and annual well check. **Updated denominator exclusions: For all collection type**: Option 1 and Option 2: Revised: 1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during 6 months prior to the measurement period through December 31 of the measurement period. 2. Patient 66 - 80 years of age and had at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. 3. Patients 66 - 80 years of age and had at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. Added: 1. Patients 81 years of age and older with at least one claim/encounter for frailty during 6 months prior to the measurement period through December 31 of the measurement period. **Updated denominator exclusion: For all collection types:** For Option 1 and Option 2: Added coding to identify patients with advanced illness and frailty **Updated definition: For all collection types:** Revised: Pharmacologic Therapy – U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis include: bisphosphonates, alendronate, alendronate-cholecalciferol, ibandronate, risedronate, zoledronic acid, teriparatide, denosumab, abaloparatide, romosozumab, and raloxifine.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to expand the eligible encounter coding for Option 1 to include all relevant encounters and create a more complete eligible patient population. We proposed that the denominator exclusion language and logic be updated in all collection types to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. A denominator exclusion was added to remove patient 81 years of age and older with a frailty encounter during the measurement period as patients within this age stratification are more appropriately assessed less stringently when determine if they should be excluded from the eligible patient population. Additionally, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We proposed to update the definition for pharmacologic therapy to align with the current U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:

Updated denominator exclusions: For all collection type: Option 1 and Option 2: Revised:

1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the six months prior to the measurement period through December 31 of the measurement period
2. Patients 66 - 80 years of age with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period
3. Patients 66 - 80 years of age with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period

Added:

1. Patients 81 years of age and older with at least one claim/encounter for frailty during the six months prior to the measurement period through December 31 of the measurement period

This additional refinement does not affect the intent of the proposed substantive change.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q418 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.90 Overuse of Imaging for the Evaluation of Primary Headache

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	419
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **Updated denominator criteria:** Removed inpatient setting. Removed "Patients with no clinical indications for imaging of the head". Added telehealth as eligible encounter. **Updated denominator instructions:** Removed denominator instructions. **Updated denominator exclusion:** Added: Patients with clinical indications for imaging of the head • Head trauma • New or change in headache above 50 years of age • Abnormal neurologic exam • Headache radiating to the neck • Positional headaches • Temporal headaches in patients over 55 years of age • New onset headache in pre-school children or younger (<6 years of age) • New onset headache in pediatric patients with disabilities for which headache is a concern as inferred from behavior • Occipital headache in children • Thunderclap headache • Trigeminal pain • Persistent headaches **Updated denominator exception:** Revised: Imaging needed as part of a clinical trial; or other clinician ordered the study.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type. The limited adoption of the quality measure for this collection type does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. We proposed to update the denominator criteria to remove the inpatient setting as this measure is appropriate for the outpatient setting only. We proposed to remove the denominator criteria for patients with no clinical indications for head imaging and replace it with a denominator exclusion that clarifies patients with clinical indications for whom imaging of the head would be clinically relevant and warranted. The denominator instructions were removed as they were duplicative of the added denominator exclusion. Additionally, we proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. The denominator exception is being updated to delete outdated language and no longer allows for system reason(s).

Comment: One commenter requested the removal of Medicare Part B Claims Measure Specifications for measure Q419 through the measure review process. The commenter noted that these changes were not reflected in the 2021 PFS proposed rule and the measure specifications should be removed, as the measures steward is no longer maintaining these specifications. A second commenter opposed the removal of the Claims collection type because it would adversely impact ophthalmologists, particularly those in small and rural practices who must rely on the claims reporting collection type because they cannot afford to adopt CEHRT.

Response: We refer the commenter to the substantive change proposed to include a modification to the collection type resulting in the removal of the Medicare Part B Claims Measure Specification. We thank the commenter for their support in the removal of the Medicare Part B Claims Measure Specification collection type.

Comment: One commenter supported and one commenter did not support the addition of telehealth reporting for measure Q419.

Response: We believe that including telehealth encounters as denominator eligible as this will lead to a more complete patient population to ensure appropriate use of imaging for a diagnosis of primary headache. We encourage the commenter who did not support adding telehealth to this measure to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q419 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.91 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
NQF # / eCQM NQF #:	2152 / N/A
Quality#:	431
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.
Substantive Change:	**The description is revised to read:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user. **Updated instructions:** Revised: For the purposes of the measure, the most recent denominator eligible encounter should be used to determine if the numerator action for the submission criteria was performed within the 12-month look back period. Added: This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months 2) Percentage of patients aged 18 years and older who were identified as unhealthy alcohol users who received brief counseling 3) Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as unhealthy alcohol users The denominator of submission criteria 2 is a subset of the resulting numerator for submission criteria 1, as submission criteria 2 is limited to assessing if patients identified as unhealthy alcohol users received brief counseling. For all patients, submission criteria 1 and 3 are applicable, but submission criteria 2 will only be applicable for those patients who are identified as unhealthy alcohol users. Therefore, data for every patient that meets the age and encounter requirements will only be submitted for submission criteria 1 and 3, whereas data submitted for submission criteria 2 will be for a subset of patients who meet the age and encounter requirements, as the denominator has been further limited to those who were identified as unhealthy alcohol users. THERE ARE THREE SUBMISSION CRITERIA FOR THIS MEASURE: 1) All patients who were screened for unhealthy alcohol use using a systematic screening method AND 2) All patients who were identified as unhealthy alcohol users who received brief counseling AND 3) All patients who were screened for unhealthy alcohol use using a systematic screening method and, if identified as unhealthy alcohol users received brief counseling, or were not identified as unhealthy alcohol users This measure contains three submission criteria which aim to identify patients who were screened for unhealthy alcohol use using a systematic screening method (submission criteria 1), patients who were identified as unhealthy alcohol users and who received brief counseling (submission criteria 2), and a comprehensive look at the overall performance on unhealthy alcohol use screening and brief counseling (submission criteria 3). By separating this measure into various submission criteria, the MIPS eligible professional or MIPS eligible clinician will be able to better ascertain where gaps in performance exist, and identify opportunities for improvement. The overall rate (submission criteria 3) should be utilized to compare performance to published versions of this measure prior to the 2021 performance year, when the measure had a single performance rate. For accountability reporting in the CMS MIPS program, the rate for submission criteria 2 is used for performance. **The denominator is revised to read:** Submission Criteria 1: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period. Submission Criteria 2: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period who were screened for unhealthy alcohol use and identified as an unhealthy alcohol user. Submission Criteria 3: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period. **Updated denominator:** Added telehealth as eligible encounter. **The numerator is revised to read:** Submission Criteria 1: Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. Submission Criteria 2: Patients who received brief counseling. Submission Criteria 3: Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within 12 months AND who received brief counseling if identified as an unhealthy alcohol user. **The numerator definition is revised to read**: Submission Criteria 1: Systematic screening method – For purposes of this measure, one of the following systematic methods to assess unhealthy alcohol use must be utilized. Systematic screening methods and thresholds for defining unhealthy alcohol use include: • AUDIT Screening Instrument (score ≥ 4) • AUDIT-C Screening Instrument (score ≥ 4 for men; score ≥ 3 for women) • Single Question Screening - How many times in the past year have you had 5 (for men) or 4 (for women and all adults older than 65 years) or more drinks in a day? (response ≥ 1). Submission Criteria 2 and 3: Brief counseling – Brief counseling for unhealthy alcohol use refers to one or more counseling sessions, a minimum of 5-15 minutes, which may include: feedback on alcohol use and harms; identification of high risk situations for drinking and coping strategies; increased motivation and the development of a personal plan to reduce drinking.

Category	Description
	Updated numerator note: Submission Criteria 1: Added: To satisfy the intent of this measure, a patient must have at least one screening for unhealthy alcohol use during the 12-month period. If a patient has multiple screenings for unhealthy alcohol use during the 12-month period, only the most recent screening, which has a documented status of unhealthy alcohol user or unhealthy alcohol non-user, will be used to satisfy the measure requirements. Submission Criteria 2: Added: In the event that a patient is screened for unhealthy alcohol use and identified as an unhealthy user but did not receive brief alcohol cessation counseling submit GXXXX. Denominator Exception(s) are determined on the date of the most recent denominator eligible encounter for all submission criteria. Submission Criteria 3: Added: To satisfy the intent of this measure, a patient must have at least one unhealthy alcohol use screening during the 12-month period. If a patient has multiple unhealthy alcohol use screenings during the 12-month period, only the most recent screening, which has a documented status of unhealthy alcohol user or unhealthy alcohol non-user, will be used to satisfy the measure requirements. In the event that a patient is screened for unhealthy alcohol use and identified as an unhealthy user but did not receive brief alcohol cessation counseling submit G9624. Denominator Exception(s) are determined on the date of the most recent denominator eligible encounter for all submission criteria. **Updated numerator options:** **Submission Criteria 1:** Revised: **Performance Met:** Patient identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method. **Performance Not Met:** Patient not screened for unhealthy alcohol use using a systematic screening method, reason not given. **Submission Criteria 2:** Added: **Performance Met:** Patient identified as an unhealthy alcohol user received brief counseling. **Denominator Exception:** Documentation of medical reason(s) for not providing brief counseling (e.g., limited life expectancy, other medical reasons). **Performance Not Met:** Patient did not receive brief counseling if identified as an unhealthy alcohol user, reason not given. **Submission Criteria 3:** **Performance Met:** Patient identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method and received brief counseling. **Performance Met:** Patient not identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method. **Denominator Exception:** Documentation of medical reason(s) for not screening for unhealthy alcohol use (e.g., limited life expectancy, other medical reasons). **Denominator Exception:** Documentation of medical reason(s) for not providing brief counseling if identified as an unhealthy alcohol user (e.g., limited life expectancy, other medical reasons). **Performance Not Met:** Patient not screened for unhealthy alcohol use using a systematic screening method OR patient did not receive brief counseling if identified as an unhealthy alcohol user, reason not given. **Updated performance rate calculation:** Revised into three submission criteria. Submission Criteria 2 will be used for benchmarking purposes.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure overall by splitting the measure into separate populations for three submission criteria. This will allow MIPS eligible clinicians to more readily find where the gaps in performance lie, allowing them to be better informed and able to adjust to improve quality care and patient outcomes. We proposed to revise the measure to shorten the look back period to 12 months and require that unhealthy alcohol screening who received brief counseling, if patient screened positive, occur every 12 months. The revision is based upon stakeholder feedback and input from the eCQM Clinical Review Process (CRP) and the measure steward's technical expert panel (TEP) and we agreed that it is important to do this annually excessive alcohol use is one of the most common causes of premature mortality in the United States (https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/unhealthy-alcohol-use-in-adolescents-and-adults-screening-and-behavioral-counseling-interventions). The numerator definition for Systematic screening method has been revised to align with current recommendations for the AUDIT C and the Single Questions Screening threshold. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
Comment: Several commenters supported the addition of telehealth reporting for measure Q431. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q431 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.92 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v4
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications **Updated denominator logic: For the eCQM Specifications collection type:** Added "CABG, PCI Procedure" 2.16.840.1.113762.1.4.1138.566 value set. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Added Hospice Care value sets. **The numerator definition is revised to read: For the MIPS CQMs Specifications collection type**: Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage): Atorvastatin, Fluvastatin, Lovastatin (Mevinolin), Pitavastatin, Pravastatin Sodium, Rosuvastatin Calcium, Simvastatin, Amlodipine Besylate/Atorvastatin, Ezetimibe/Simvastatin **Updated denominator note: For the MIPS CQMs Specifications collection type**: Revised: Denominator Exclusions should be active at any time during the measurement period. **Updated denominator: For the MIPS CQMs Specifications collection type:** Added telehealth as eligible encounters for all submission criteria.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a value set to the eCQM Specifications collection type denominator to allow for the use of CPT and HCPCS codes for reporting patients who have had a CABG or PCI for inclusion within the denominator. This will improve data capture to ensure a more complete patient population. Additionally, a Hospice Care value set was added to align with the measure intent to exclude both palliative care and hospice patients. We proposed to add telehealth encounters as denominator eligible for the MIPS CQMs Specifications collection type as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to add the numerator definition for the MIPS CQMs Specifications collection type to include a table of medications within this section and not in the clinical recommendations statement to ensure MIPS eligible clinicians are following these recommendations based on the clinical guidelines. Additionally, we proposed to update the denominator note to add clarity regarding when the denominator exclusion would be assessed within the medical record for the purposes of reporting this measure. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: Several commenters supported the addition of telehealth reporting for measure Q438.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.
Comment: One commenter was not opposed to CMS being more prescriptive with the qualifying medications as long as frequent updates are made to the acceptable medications list.

Response: We thank the commenter for supporting the substantive change to the medication list for measure Q438.

After consideration of public comments, we are finalizing the changes to measure Q438 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Measure Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Measure Specifications. Also, it should be noted that the CMS Web Interface Specifications collection type is not able to establish a benchmark for this measure. Thus, this measure will be excluded from the Merit-based Incentive Payment System (MIPS) scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the measure meets the data completeness requirement and the data applicable to the measure is reported via the CMS Web Interface Measure Specifications.

D.93 Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.
Substantive Change:	**The description is revised to read:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31. **The denominator is revised to read:** All screening colonoscopy examinations performed on patients greater than or equal to 50 years of age during the encounter period. **Updated denominator criteria:** Revised: All patients greater than or equal to 50 years of age on date of encounter receiving a colonoscopy for screening purposes only. **The numerator is revised to read:** Screening colonoscopies performed in patients greater than or equal to 86 years of age. **The numerator options are revised to read:** **Performance Met:** Patients greater than or equal to 86 years of age who underwent a screening colonoscopy and did not have a history of colorectal cancer or other valid medical reason for the colonoscopy, including: iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits. **Denominator Exception:** Documentation of medical reason(s) for a colonoscopy performed on a patient greater than or equal to 86 years of age (e.g., iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial history of adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits). **Performance Not Met:** Patients greater than or equal to 86 years of age who received a colonoscopy for an assessment of signs/symptoms of GI tract illness, and/or because the patient meets high risk criteria, and/or to follow-up on previously diagnosed advanced lesions. **Performance Not Met:** Patients between 50 and 85 years of age who received a screening colonoscopy during the performance period.
Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to update the denominator population to include all patients aged 50 and older to ensure a more complete patient population as the intent of the measure is to assess age appropriate screening colonoscopies, which include patients under the age of 86 years. The description, denominator, and denominator criteria have been updated to reflect these revisions. The numerator and numerator options have been revised to more clearly reflect the patient population and a performance not met numerator option was added to reflect the expanded denominator eligible patient population. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

We proposed a substantive change to the numerator options; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
The numerator options are revised to read:
Performance Met: Patients greater than or equal to 86 years of age who underwent a screening colonoscopy and did not have a history of colorectal cancer or other valid medical reason for the colonoscopy, including: iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits.
Performance Not Met: Documentation of medical reason(s) for a colonoscopy performed on a patient greater than or equal to 86 years of age (e.g., iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial history of adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits).
Performance Not Met: Patients greater than or equal to 86 years of age who received a colonoscopy for an assessment of signs/symptoms of GI tract illness, and/or because the patient meets high risk criteria, and/or to follow-up on previously diagnosed advanced lesions.
Performance Not Met: Patients between 50 and 85 years of age who received a screening colonoscopy during the performance period.

This additional refinement of changing the Denominator Exception to a Performance Not Met does not affect the intent of the proposed substantive change. This revision aligns with the current measure specification and will not affect the final performance as this is an inverse measure. It is just a reclassification of the numerator option.

Comment: One commenter supported the changes to measure Q439.

Response: We thank the commenter for supporting the changes to this measure.
After consideration of public comments, we are finalizing the changes to measure Q439 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.94 Medication Management for People with Asthma

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	444
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.
Substantive Change:	**Updated numerator:** Updated medication table to split medications by controller versus reliever and adding 'Medication List' and 'Route' column. Asthma Controller Medications: Dyphylline-guaifenesin, Omalizumab, Benralizumab, Mepolizumab, Reslizumab, Budesonide-formoterol, Fluticasone-salmeterol, Fluticasone-vilanterol, Formoterol-mometasone, Beclomethasone, Budesonide, Ciclesonide, Flunisolide, Fluticasone, Mometasone, Montelukast, Zafirlukast, Zileuton, Theophylline. Asthma Reliever Medications: Albuterol, Levalbuterol.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the medications table to ensure the list includes current and appropriate medications for the purposes of meeting performance of this measure. The measure specification medication tables were reformatted for clarity and readability.

Comment: One commenter encouraged CMS to double check the list of medications for completeness for this measure.

Response: We thank the commenter for their comment. This list has been reviewed for accuracy; however, we encourage the commenter to reach out to the measure steward regarding the medication list for potential revisions for possible inclusion in future years.

After consideration of public comments, we are finalizing the changes to measure Q444 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.95 Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

Category	Description
NQF # / eCQM NQF #:	1858 / N/A
Quality#:	450
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving Trastuzumab.
Substantive Change:	**The title is revised from 'Trastuzumab received by patients with AJCC stage I (T1c) - III and HER2 positive breast cancer receiving adjuvant chemotherapy' to:** Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer. **The description is revised to read**: Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated. **The denominator is revised to read**: All female breast cancer patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer. **Updated denominator criteria**: Revised: Female patients age 18-70 years on date of encounter. Removed: Breast Adjuvant Chemotherapy administered. **Updated denominator exclusions:** Removed: • Patient transferred to practice after initiation of chemotherapy. • Patient has metastatic disease at diagnosis. Added: • Patients with pregnancy during adjuvant treatment course. **The numerator is revised to read:** Patients whose adjuvant treatment course includes both chemotherapy and HER2-targeted therapy. **The numerator note is revised to read**: The quality action of this measure is the appropriateness of treatment rather than timeliness of treatment. The timing of administration of HER2-targeted therapies is expected to vary depending on the cytotoxic agents used. The numerator statement is intended to capture an adjuvant treatment course that includes both chemotherapy and HER2-targeted therapy, independent of possible administration sequences. Adjuvant chemotherapy is defined as a chemotherapy regimen initiated within 6 months of cancer diagnosis. An FDA-approved trastuzumab biosimilar is an appropriate substitute for trastuzumab. **The numerator options are revised to read:** **Performance Met:** Patient received adjuvant treatment course including both chemotherapy and HER2-targeted therapy. **Denominator Exception:** Reason for not administering adjuvant treatment course including both chemotherapy and HER2-targeted therapy (e.g. poor performance status (ECOG 3-4; Karnofsky ≤50), cardiac contraindications, insufficient renal function, insufficient hepatic function, other active or secondary cancer diagnoses, other medical contraindications, patients who died during initial treatment course or transferred during or after initial treatment course). **Performance Not Met:** Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to expand the scope and clinical focus of the measure to include all female patients age 18 – 70 years with stage I (T1c) - III HEr2 positive breast cancer, allowing for assessment of chemotherapy within the numerator, necessitating the removal of the denominator criteria for chemotherapy. NCCN recommendations support the administration of chemotherapy and trastuzumab for this patient population. We proposed to remove the current denominator exclusions and add new denominator exclusions based upon feasibility testing which determined these histologies are rare enough and are unlikely to have HER2 positivity such that it is not necessary to specifically target for removal from the denominator population. We agreed that these exclusions are not appropriate for inclusion. The added denominator exclusions reflect the measure's change in clinical scope and allows for removal of patients for whom treatment with chemotherapy and HER2-targeted therapy would not be appropriate. The measure steward's technical expert panel acknowledged that patients who fail to receive timely treatment may also fail to receive appropriate treatment. Because the quality action of this measure is appropriateness rather than timeliness of treatment, a broader timeframe is utilized to capture patients who may be less likely to receive appropriate treatment, therefore, 6 months was chosen to define adjuvant chemotherapy. The inclusion of an FDA-approved trastuzumab biosimilar as substitute for trastuzumab is in accordance with updated NCCN breast cancer guidelines. We agreed with this revision to the numerator note as it clarifies the updated measure scope and aligns with current clinical guidelines. Additionally, we proposed to update the numerator options to reflect the updated scope and clinical focus of the measure. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
We received no public comments on the substantive changes propose for this measure; therefore, we are finalizing the changes to measure Q450 as proposed for	

Category	Description
the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.96 RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

Category	Description
NQF # / eCQM NQF #:	1859 / N/A
Quality#:	451
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q451 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.97 Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Category	Description
NQF # / eCQM NQF #:	1860 / N/A
Quality#:	452
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q452 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.98 Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0210 / N/A
Quality#:	453
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q453 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.99 Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0213 / N/A
Quality#:	455
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q455 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.100 Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0216 / N/A
Quality#:	457
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

Comment: One commenter was concerned about adding a telehealth exclusion to measure Q457 because CMS claimed that telehealth encounters were not applicable to this measure. The commenter disagreed with this statement and believed it would be appropriate to include telehealth encounters in this measure. This measure aims to identify patients who either did not have a hospice referral prior to death or received hospice care too late. Including telehealth encounters would help CMS to more comprehensively and accurately identify patients who were unable to benefit from hospice services.

Response: We thank the commenter for their comment. This measure currently requires two or more encounters at the reporting site and that the patient be enrolled in hospice as part of the denominator eligibility criteria. The inclusion of a telehealth modifier exclusion for the patient encounters aligns with the intent of the measure. To be eligible for this measure, the patient must already be enrolled in hospice. This measure assesses whether or not patients were enrolled in hospice in a timely manner in order to maximize benefits that may be attained from this service. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q457 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.101 Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q459 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.102 Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q460 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.103 Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q461 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.104 Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	462
CMS eCQM ID:	CMS645v4
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**Updated definition:** Added: First Androgen Deprivation Therapy - The First Androgen Deprivation Therapy (ADT) is measured as the first order or administration of ADT for an anticipated period of 12 months or greater to a patient with prostate cancer.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a definition for 'First Androgen Deprivation Therapy' to clarify the timing of the bone density evaluation necessary for numerator compliance.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q462 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.105 Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	0657 / N/A
Quality#:	464
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

Comment: One commenter supported the addition of telehealth reporting for measure Q464. The commenter noted that there is an error in the substantive change: "Updated denominator: Added telehealth exclusion to patient encounter." The substantive change should instead read, "Updated denominator: Telehealth exclusion to patient encounter is removed" as telehealth encounters are applicable to this measure and these patients should not be excluded in the denominator.

Response: We agree that the measure specification currently excludes telehealth and the substantive change was to remove the telehealth exclusion as it would be appropriate to include these patients into the measure denominator eligible population.

After consideration of public comments, we are finalizing the changes to measure Q464 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.106 Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	468
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.
Substantive Change:	**Updated instructions:** Revised: This measure is to be submitted a minimum of once per performance period for all adults aged 18 years and older with pharmacotherapy for OUD seen during the measurement period that meet additional denominator criteria described below. **The denominator is revised to read:** Adults aged 18 years and older who had a qualifying encounter during the performance year, and a diagnosis of OUD and pharmacotherapy for OUD during the denominator identification period. Eligibility to submit results for a patient requires a qualifying encounter in the performance year, i.e., between January 1, 2021, and December 31, 2021. Solely administering or prescribing OUD medication does not convey eligibility to submit. If a patient has a qualifying encounter within the performance year, the patient is included in the denominator, if the following criteria are met in the denominator identification period between July 1, 2020, and June 30, 2021: • Have a diagnosis of OUD • Receive pharmacotherapy for OUD **Updated denominator definition:** Added: Qualifying Encounter – Encounter during the performance year. Revised: Denominator Identification Period – The period in which eligible adults receive pharmacotherapy for OUD. The denominator identification period is defined as the 12-month period from 07/1/2020 to 6/30/2021. The denominator identification period includes the first 6 months of the reporting year and the last 6 months of the previous year to ensure that all included patients can be observed for at least 180 days of treatment in the reporting year. Patients started on treatment in the second half of the reporting year will be included in the denominator of the subsequent year. The patient must have at least one OUD medication and one visit with a OUD diagnosis during the denominator identification period to be eligible for the measure. **Updated denominator criteria:** Revised: Adults aged ≥ 18 years on date of qualifying encounter. Encounter during the measurement period. **Updated denominator exclusion:** Removed: Pharmacotherapy for OUD initiated after June 30th of 2020. **The numerator note is revised to read:** Numerator compliance is expected to be determined within an 18-month period that includes the measurement period and the 6 months prior to the measurement period (July 1, 2020– December 31, 2021).
Steward:	University of Southern California
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure to ensure the denominator eligible encounter occurs within the current performance period and the initiation of pharmacotherapy for opioid use disorder (OUD) occurs within the denominator identification period to allow for assessment of at least 180 days for continuous pharmacotherapy for OUD. Additionally, we aproposed to update the definitions by adding an additional definition of qualifying encounter to clarify which encounters are denominator eligible and revising the denominator identification period definition to align with and clarify the changes to the denominator in regards to timing and eligibility. The numerator note is being revised to align with these changes outlined above and reiterates the guidance pertaining to the timeframes allowed for clinicians to determine if the patient was on at least 180 days for continuous. pharmacotherapy for OUD
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q468 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.107 Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q469 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.108 Functional Status After Primary Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	470
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively.
Substantive Change:	**The description is revised to read:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively. **Updated instructions:** Revised: NOTE: This measure is a target-based measure, where the numerator is met by having a one-year postoperative Oxford Knee Score (OKS) greater than or equal to 37 or a KOOS, JR score greater than or equal to 71. It is expressed as a proportion or rate. Patients having received a primary total knee replacement procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures for performance calculation. **The numerator is revised to read**: All eligible patients whose functional status is greater than or equal to 37 on the Oxford Knee Score (OKS) or greater than or equal to 71 on the KOOS, JR patient reported outcome tool at one year (9 to 15 months) postoperatively. **Updated numerator definition:** Added: KOOS, JR - The KOOS, JR was developed from the original long version of the Knee injury and Osteoarthritis Outcome Score (KOOS) survey using Rasch analysis. The KOOS, JR contains 7 items from the original KOOS survey. Items are coded from 0 to 4, none to extreme respectively. KOOS, JR is scored by summing the raw response (range 0-28) and then converting it to an interval score using the table provided below. The interval score ranges from 0 to 100 where 0 represents total knee disability and 100 represents perfect knee health. This short form tool was developed by Stephen Lyman, PhD at the Hospital for Specialty Surgery in 2017. https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp KOOS, JR Target - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status score as greater than or equal to 71. **The numerator note is revised to read:** The following situations are those in which the numerator targets cannot be reached and Performance Not Met (M1046) is submitted: • Oxford Knee Score (OKS) or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is not administered postoperatively at one year (9 to 15 Months) • Functional status is measured using a different patient-reported functional status tool or Oxford Knee Score (OKS) version or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) • Postoperative Oxford Knee Score (OKS) or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is administered less than 9 Months or greater than 15 Months • Postoperative Oxford Knee Score (OKS) is less than 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is less than 71. **The numerator options are revised to read:** **Performance Met:** Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was greater than or equal to 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was greater than or equal to 71. **Performance Not Met:** Functional status measured by the Oxford Knee Score (OKS) or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) at one year (9 to 15 months) postoperatively was less than 37. **Performance Not Met:** Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was less than 37 or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was less than 71.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the measure to allow for the inclusion of the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) tool as numerator compliance. The KOOS, JR is recommended by the American Academy of Orthopaedic Surgeons (AAOS) and is part of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation and is an appropriate tool for the purposes of this measure. The language was updated throughout the measure to reflect this update and to define numerator compliance when utilizing the KOOS, JR tool.

We proposed a substantive change to numerator options; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
Performance Met: Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was greater than or equal to 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was greater than or equal to 71.
Performance Not Met: Functional status was not measured by the Oxford Knee Score (OKS) or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR.) at one year (9 to 15 months) postoperatively
Performance Not Met: Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was less than 37 or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was less than 71.
This additional refinement does not affect the intent of the proposed substantive change, but is in alignment with the updates to the entire measure and the guidance given in the numerator note.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q470 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.109 Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q471 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.110 Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q473 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.111 International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v2
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**The title is revised from 'International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia' to:** Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Large Urology Group Practice Association and Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to shorten the title to replace the very specific score wording with more general wording to be more consistent with definitions and language used within the measure. We proposed to remove telehealth encounters from the denominator and denominator exclusions as telehealth is not an appropriate setting for this measure. This guidance can be found in a separate document that will be published on the eCQI Resource Center.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q476 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.112 Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	478
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).
Substantive Change:	**The description is revised to read:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil). **The definition is revised to read**: **Functional Deficit** – Limitation or impairment of physical abilities/function resulting in evaluation and inclusion in a treatment plan of care. **Treatment Episode** –A Treatment Episode is defined as beginning with an Initial Evaluation for a functional neck deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a neck deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Initial Evaluation** – An Initial Evaluation is the first encounter for a functional deficit involving the neck and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code (M1143). A patient presenting with a neck impairment, who has had an interruption of a Treatment Episode for the same functional neck deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. **Discharge**– Discharge is accompanied by a treatment finalization and evaluation completion M-Code (Mxxx) identifying the close of a Treatment Episode for the same neck deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. **Encounter** – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. Patient Reported – The patient directly provides answers to the FS measure items using a standardized, reliable and valid, computerized adaptive testing or short form (static/paper and pencil-type) method. If the patient cannot reliably respond independently (for example, in the presence of cognitive deficits), a suitable proxy may provide answers. **The denominator is revised to read**: All patients aged 14 years and older with neck impairments who initiated a Treatment Episode. **Updated denominator criteria**: Revised: All patients aged ≥14 years on date of Initial Evaluation. Added: With a neck impairment and/or diagnosis pertaining to a functional deficit affecting the neck. **Updated denominator** exclusions: Removed: Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Added: Patient unable to complete the Neck FS PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility, and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the Neck FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **The numerator definition is revised to read:** **Patient's Functional Status Score** – A functional status score is produced when the patient completes the functional status patient-reported outcome measure (either by short form or computerized adaptive testing administration). The functional status score is continuous and linear. Scores range from 0 to 100 with higher scores meaning higher functional abilities. The measure is standardized, and the scores are validated for the measurement of function for this population. **Patient's Functional Status Change Score** – A functional status change score is calculated by subtracting the Patient's Functional Status Score at Initial Evaluation from the Patient's Functional Status Score at Discharge. **Predicted Functional Status Change Score** – Functional Status Change Scores for patients are risk adjusted using multiple linear regression methods that include the following independent variables: Patient's Functional Status Score at Initial Evaluation, patient age, symptom acuity, surgical history, gender, specific co- morbidities, use of medication for the condition at Initial Evaluation, exercise history, history of previous treatment for the condition and type of post-surgical status. The Patient's Functional Status Change Score is the dependent variable. For each patient completing a functional status assessment at Initial Evaluation (Intake), the regression model provides a risk-adjusted prediction of functional status change at Discharge. **Risk-Adjusted Functional Status Change Residual Score** – The difference between the raw non-risk- adjusted Patient's Functional Status Change Score and the Risk-Adjusted Predicted Functional Status Change Score (raw minus predicted) is the Risk-Adjusted Functional Status Change Residual Score, which is in the same units as the Patient's Functional Status Scores, and should be interpreted as the unit of functional status change different than predicted given the risk-adjustment variables of the patient being treated. As such, the Risk-Adjusted Residual Change Score represents Risk-Adjusted Change corrected for the level

Category	Description
	of severity of the patient. Risk-Adjusted Residual Change Scores of zero (0) or greater (> 0) should be interpreted as functional status change scores that were predicted or better than predicted given the risk- adjustment variables of the patient, and risk-adjusted residual change scores less than zero (< 0) should be interpreted as functional status change scores that were less than predicted given the risk-adjustment variables of the patient. Aggregated Risk-Adjusted Residual Scores allow meaningful comparisons amongst clinicians or clinics. **Updated numerator note:** Removed all. **The numerator options are revised to read:** **Performance Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment successfully calculated and the score was equal to zero (0) or greater than zero (> 0) **Denominator Exceptions:** 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown. 4. Patient refused to participate. **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment not measured because the patient did not complete the Neck FS PROM at Initial Evaluation and/or near Discharge, reason not given. **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment successfully calculated and the score was less than zero (< 0).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the measure to align with the other Focus on Therapeutic Outcomes, Inc. (FOTO) measures within MIPS. This will lessen MIPS eligible clinician burden when reporting this measure in conjunction with FOTO's other measures as the structure and content will now align. Definitions were inlcuded to add clarity and provide guidance when reporting this measure. Additonal denominator criteria for patients with a neck impairment and/or diagnosis pertaining to a functional deficit affect the neck was included to further define the appropriate patient population for this measure. Additionally, the denominator exclusions and exceptions were updated, along with the other numerator options, to align across all FOTO measures for consistency. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q478 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.113 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	048
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640.
After consideration of public comments received under Table C.2, we are finalizing the removal of measure Q048 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years for the Medicare Part B Claims Specifications collection type only. Measure Q048 will remain in the MIPS program for 2021 for the MIPS CQMs Specifications collection type.	

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES
Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes. In addition, some comments summarized below are out-of-scope to our proposed changes to the MIPS quality measure set.
Comment: One commenter was supportive of the proposal to remove 14 quality measures that do not add value to the quality of care, and instead add more meaningful measurements. **Response:** We thank the commenter for supporting the removal of measures from the MIPS program that do not add value to the quality of care.
Comment: One commenter recommended maintaining the existing MIPS quality measures to ensure consistency, reduce a burden, and allow options in the future for MVPs. **Response:** We understand that ensuring there are measures available for future use in MVPs is important; however, we strive to ensure that all measures align with the Meaningful Measures Initiative, which includes removing those measures that are duplicative, extremely topped out or at the end of the topped out lifecycle, no longer in alignment with the current clinical guidelines, or where a meaningful benchmark cannot be created. By removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. We encourage stakeholders to submit potential new measures that will align with the Meaningful Measures Initiative and allow MIPS eligible clinicians to maximize their potential performance within MIPS during the annual Call for Measures.
Comment: One commenter stated that CMS is proposing to expand the list of telehealth visits that include quality and cost measures in 2021. The commenter supported having expanded telehealth services. However, inclusion in the denominator across its measures does not translate to numerator compliance. There is certainly impact to administrative burden, and the commenter wanted to ensure data is captured and mapped appropriately for reporting. Use of telemedicine services for important clinical conditions is not yet fully understood. Some types of quality measurements (numerator compliance) may not be easily obtained via telemedicine or require additional infrastructure development such as remote monitoring. There should be additional time for adaptation. **Response:** We thank the commenter for their comment. Each year the measure specifications are revised and reviewed to ensure coding updates and the inclusion of telehealth encounters aligns with the measure's intent, are clinically appropriate and applicable, and are feasible for implementation. The allowance of telehealth for denominator eligibility does not translate into numerator compliance, as some quality actions are not able to be performed via telehealth, however, it is important to ensure a complete patient population is assessed for numerator compliance therefore supporting the assessment of providing quality care. We encourage the commenter to reach out to measure stewards to review expanding telehealth as a possible revision for implementation in future years and review the 2021 MIPS specifications to determine if or how telehealth is included within the measure
Comment: One commenter indicated that in terms of numerator compliance, CMS guidance has stated that there may be instances where the quality action cannot be completed during the telehealth visit. If an eligible clinician is providing services via telehealth but unable to complete the quality action in the numerator via telehealth, the commenter strongly believes that measure should be excluded from the list of telehealth eligible measures. **Response:** We agree that there are some measures available via the eCQM Specifications collection type that include telehealth encounters as denominator eligible with a quality action that cannot be met via telehealth. This decision is driven by how each measure is structured and ensuring a complete and appropriate patient population. Measures that do not require a quality action for every encounter, but allow for patient report, look back periods, or completion at encounter, would be appropriate for inclusion of telehealth. For measures that have defined performance or assessment of the quality action (e.g., measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented), telehealth encounters would not be appropriate. We would encourage the commenter to review 2021 eCQM guidance found on the eCQI Resource Center at https://ecqi.healthit.gov/ep-ec?globalyearfilter=2020.
Comment: Current eCQM standards do not allow for the use of modifiers and therefore do not clearly include or exclude telehealth encounters when these "'telehealth-eligible' CPT and HCPCS codes are used. **Response:** We do recognize that value sets by eCQMs do not include codes modifiers and would encourage stakeholders to review the 2021 eCQM guidance found on the eCQI Resource Center. In instances where a modifier is submitted, the code is used by the eCQM, however the modifier is not. As such, eCQM logic and value sets do not differentiate between in-person encounters or telehealth encounters when these "telehealth-eligible" codes are applied. Therefore, it is the eligible professionals' and eligible clinicians' responsibility to make sure they can meet all other aspects of the quality action within the measure specification, including other quality actions that cannot be completed via telehealth when considering which measure to report. And, that the encounter, either in-person or via telehealth, is in alignment with current measure specification level guidance. In instances where a POS modifier is applied for billing and is submitted for the eCQM, only the encounter code is used by the eCQM and the modifier is not used.

APPENDIX 2: IMPROVEMENT ACTIVITIES

NOTE: In this final rule, for the CY 2021 performance period and future years, we are modifying two previously adopted improvement activities in the Inventory, removing one previously adopted improvement activity, and finalizing one improvement activity that was originally adopted in the March 31st COVID-19 IFC (85 FR 19277) and continued with modification in the September 2nd COVID-19 IFC (85 FR 54850 through 54851). These improvement activities are discussed in detail below.

Table A: Changes to Previously Adopted Improvement Activities for the MIPS CY 2021 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_BE_4**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Engagement of patient through implementation of improvements in patient portal
Current Activity Description:	Access to an enhanced patient portal that provides up to date information related to relevant chronic disease health, blood pressure control, and includes interactive features allowing patients to enter health information and/or enables bidirectional communication about medication changes and adherence.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 QPP final rule (81 FR 77825). This modification would add language to include caregivers as additional potential users of the patient portal, instead of just patients and clinicians, given the important role caregivers can play in bidirectional information exchange regarding the clinical care of the patient. This modification would also add language to clarify that the portal's use should be for "bidirectional information exchange between the patient and their provider" and "the primary use…should be clinical, and not administrative." In addition, the modifications would replace existing description with a nonexhaustive list of examples of bidirectional portal functions that are clinical rather than administrative. The list of examples would include: "brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; and any relevant acute or chronic disease management."
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include, but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.
Comments:	Several commenters supported the modification of this improvement activity. Several commenters noted that caregivers are a critical component of patient-centered care. A few commenters noted the importance of bidirectional information exchange in the provision of care.
Response:	The modification to this improvement activity includes caregivers in the bidirectional information exchange regarding the clinical care of patients and provides clarity that the portal should be used for bidirectional information exchange that is clinical not administrative in nature.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_4**
Subcategory:	Beneficiary Engagement
Activity Title:	Engagement of patient through implementation of improvements in patient portal

Activity Description:	To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include, but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_AHE_7**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Comprehensive Eye Exams
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA. This activity is intended for: ● Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; ● Ophthalmologists/optometrists caring for underserved patients at no cost; or ● Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2019 PFS final rule (83 FR 59452). This modification would add language that expands the types of services that eligible clinicians can promote to underserved and/or high-risk populations to receive credit for this activity. Specifically, we are proposing to add the following sentence: "promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment." Also, "or vision rehabilitation services" would be added to the end of the activity description. These modifications would broaden this improvement activity to eligible clinicians who promote vision rehabilitation services, if they are serving patients with vision impairments detected during comprehensive eye exams.
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by any one or more of the following: ● providing literature, ● facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign, ● referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA, or ● promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment. This activity is intended for: ● Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; ● Ophthalmologists/optometrists caring for underserved patients at no cost; or ● Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their

	access to comprehensive eye exams or vision rehabilitation services.
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the support for this modification. The modification to this improvement activity allows clinicians also to receive credit by providing vision rehabilitation services to patients who are underserved and/or high-risk with vision impairments detected during comprehensive exams.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_7**
Subcategory:	Achieving Health Equity
Activity Title:	Comprehensive Eye Exams
Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by any one or more of the following: ● providing literature, ● facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign, ● referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA, or ● promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment. This activity is intended for: ● Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; ● Ophthalmologists/optometrists caring for underserved patients at no cost; or ● Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams or vision rehabilitation services.
Weighting:	Medium

TABLE B: Improvement Activity for Removal for the MIPS CY 2021 MIPS Performance Period and Future Years

In this final rule, we are finalizing the removal of one previously finalized improvement activity from the MIPS Program for the MIPS CY 2021 performance period/2023 MIPS payment year and future years. This improvement activity is discussed in detail below. Improvement activity removal factors are discussed in the MIPS CY 2020 final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_CC_5**
Current Subcategory:	Care Coordination
Current Activity Title:	CMS Partner in Patients Hospital Engagement Network
Current Activity Description:	Membership and participation in a CMS Partnership for Patients Hospital Engagement Network.
Current Weighting:	Medium
Removal Rationale:	Subsequent to publication of the proposed rule, we became aware that the underlying program, which forms the basis for this improvement activity, has expired. The Partner in Patients Hospital Engagement Network activity description requires membership and participation in a CMS Partnership for Patients Hospital Engagement Network which ended March 31, 2020, and may be found at https://innovation.cms.gov/innovation-models/partnership-for-patients. Because the Partnership for Patients Hospital Engagement Network has ended and performance of this activity will no longer be possible starting with the CY 2021 performance year, this improvement activity is obsolete (Factor 7, 84 FR 62988) and no longer available for clinicians to participate in; therefore, we are finalizing removal of this improvement activity beginning with the CY 2021 performance year/2023 MIPS payment year to avoid any potential confusion.
Comments:	N/A – Not included in the notice of proposed rulemaking.
Response:	N/A – Not included in the notice of proposed rulemaking.
Final Action:	We are finalizing the removal of this improvement activity beginning with the CY 2021 performance year/2023 MIPS payment year.
Finalized Improvement Activity	
Activity ID:	N/A – Removed

Table C: Finalization of Improvement Activity Previously Adopted in the March 31st COVID-19 IFC (85 FR 19277) and Continued with Modification in the September 2nd COVID -19 IFC (85 FR 54850 through 54851) for the MIPS CY 2021 Performance Period

Original Improvement Activity	
Original Activity ID:	**IA_ERP_XX**
Original Subcategory:	Emergency Response and Preparedness
Original Activity Title:	COVID-19 Clinical Trials
Original Activity Description:	To receive credit for this activity, a MIPS eligible clinician must participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study. For more information on COVID-19 clinical trials we refer redears to the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. This improvement activity was finalized for the MIPS CY 2020 performance period only in response to the PHE for COVID-19.
Original Weighting:	High
Original Comments:	Several commenters supported our efforts to encourage and recognize clinician participation in COVID-related clinical trials through the finalization of this improvement activity.
Original Responses:	We appreciate the commenters' support. We believe that clinicians who treat patients diagnosed with COVID-19 and simultaneously submit relevant data regarding that patient to a clinical data registry for COVID-19 research should receive credit. We believe that all clinical data gathered in the treatment of patients diagnosed with COVID-19 may be helpful in finding a solution to end this pandemic. Encouraging clinicians collectively to utilize a clinical data registry for data reporting could facilitate sharing of data for use in additional clinical studies with larger sample sizes. These additional and larger clinical studies are likely to identify efficacy of certain treatments, which in turn could result in wider improvements in health outcomes, including reduced severity and mortality due to COVID-19 across the nation. This could benefit patients nationwide as well as improve clinical practice and care delivery for the patients of the clinician attesting to this improvement activity.
Modified Improvement Activity	
Modified Activity ID:	**IA_ERP_3**
Modified Subcategory:	Emergency Response and Preparedness
Modified Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Change and Rationale:	Following the publication of the March 31st IFC for COVID-19, we received several inquiries through meetings, email correspondence, and Quality Payment Program help desk requesting further information on whether a clinician working with COVID-19 patients who provides their data to a clinical data registry, without participating in a clinical trial, may get credit for this activity. The Quality Payment Program help desk tracks, documents, and resolves inquiries submitted by MIPS eligible clinicians and groups. Stakeholders may submit inquiries to the help desk via 1-866-288-8292 (Monday-Friday 8 a.m.-8 p.m. ET) or email *QPP@cms.hhs.gov*. Some stakeholders believed that clinicians providing care to patients with COVID-19 outside of a clinical trial that report those data through a clinical data registry should receive credit for this activity. It came to our attention that clinical data registries not only collect data as part of clinical trials, but also collect data from clinicians not participating in clinical trials. The improvement activity as written was causing confusion for clinicians and groups attempting to meet the needs of patients and address gaps in research. Since IA_ERP_3 titled "COVID-19 Clinical Trials" was established, this improvement activity has been the subject of approximately 30 percent of the inquiries to the Quality Payment Program help desk, demonstrating the desire for clinicians to improve clinical care and overall outcomes for patients diagnosed with COVID-19 by conducting this improvement activity, but also indicating the need for further clarity in its activity description. As a result, we expanded the improvement activity to include clinicians

	participating in the care of a patient diagnosed with COVID-19 who simultaneously submit their clinical patient data to a clinical data registry for research. Thus, in order to receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) Participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. We also modified the improvement activity title to reflect this change. We had previously added the improvement activity to the Inventory for the CY 2020 performance period only in response to the PHE for COVID-19. In this IFC, we extended the newly modified COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the increased rate of COVID-19 infection we were experiencing nationwide. We anticipated the need for COVID-19 clinical trials and data collection/sharing through registries to continue through CY 2021 at which time we would reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We wanted eligible clinicians to be able to attest to this improvement activity if it is still pertinent. We believed that participation in this improvement activity was likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID-19.
Modified Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publically available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213. This improvement activity was continued through the CY 2021 performance period.

Modified Weighting:	High
Comments:	In response to the September 2nd COVID-19 IFC (85 FR 54850 through 54851), several commenters supported the proposal to expand this improvement activity to include clinicians participating in the care of a patient diagnosed with COVID-19 who simultaneously submit their clinical patient data to a clinical data registry for research. Commenters noted that this expansion will increase clinician participation in this improvement activity and increase the availability of COVID-19 patient data. One commenter specifically noted this proposal will improve data for a COVID-19 registry focused on cancer patients and appreciated that a cancer registry is acceptable to meet this improvement activity. A few commenters noted support for the extension of this improvement activity into 2021. Additionally, in response to the September 2nd COVID-19 IFC, a few commenters recommended additional clarifications or expansions around the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity. One commenter requested that CMS clarify whether anyone submitting COVID-19 related data to a registry would qualify for credit for this improvement activity, whether it is a Qualified Registry (QR), Qualified Clinical Data Registry (QCDR), or a data registry that collects clinical data, provided it meets the other outlined criteria. Another commenter recommended that CMS add additional research targets to the improvement activity, including research related to diagnostic and medical devices rather than just therapeutics. One commenter noted that reporting for the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity represents an opportunity to meet Promoting Interoperability performance category requirements and recommended that CMS coordinate with both the CDC and ONC to develop common electronic case reporting (eCR) standards. In response to the PFS for the CY 2021 performance period and future years NPRM, several commenters also provided support for the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity, including extension of this improvement activity until at least the end of the 2021 reporting period. One commenter provided their disappointment that as a group reporter, they would be unable to attest to this improvement activity because they would not be able to have more than 50 percent of their group participate in clinical data reporting.
Response:	We appreciate the commenters support for the improvement activity. We believe that this improvement activity will increase clinical data reporting and ultimately improve the collection of data clinicians use for the care of their patients. We anticipate that clinical data gathered in the treatment of patients with COVID-19 may be helpful in finding a solution to end this pandemic. To clarify, to receive credit for this improvement activity, a MIPS eligible clinician or group must either: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research If the clinician or group is participating in a COVID-19 clinical trial, it must utilize a drug or biological product. On the other hand, the clinician or group could participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. This latter option is more broad and could include use of diagnostics and medical devices. In addition, for purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. We refer readers to the activity description for full details. In many cases, this could include a Qualified Registry (QR), Qualified Clinical Data Registry (QCDR), or a data registry that collects clinical data, so long as it meets the stated requirements. We will take into consideration the recommendation that we coordinate with CDC and ONC to develop common electronic case reporting (eCR) standards related to this improvement activity. We understand the disappointment that this improvement activity is more difficult for group reporters to attest.

Final Action:	After consideration of the public comments received, we are adopting this improvement activity as finalized in the September 2nd COVID-19 IFC (85 FR 54850 through 54851) to apply through the CY 2021 performance year.
Finalized Improvement Activity	
Activity ID:	**IA_ERP_3**
Subcategory:	Emergency Response and Preparedness
Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data should be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publically available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.
Weighting:	High

[FR Doc. 2020–26815 Filed 12–2–20; 4:15 pm]
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